EXHIBIT "A"

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ASSESSMENT OF DAMAGES HEARING

[ ] IS [X] IS NOT REQUIRED

[X] JURY [ ] NON JURY

Attorneys for Plaintiffs

AETNA INC. AND AETNA HEALTH MANAGEMENT, LLC

Plaintiffs,

v.

INSYS THERAPEUTICS, INC., MICHAEL L. BABICH, ALEC BURLAKOFF, MICHAEL J. GURRY, RICHARD M. SIMON, SUNRISE LEE, JOSEPH A. ROWAN, STEVE FANTO, MAHMOOD AHMAD, AND JOHN DOES 1-10.

Defendants.

PHILADELPHIA COUNTY COURT OF COMMON PLEAS

TRIAL DIVISION

September 2017

No. 170602779

COMPLAINT – CIVIL ACTION
(KT – DISPUTE RE: BUSINESS TORT)

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after the complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiffs. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

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Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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Attorneys for Plaintiffs

AETNA INC. AND AETNA HEALTH MANAGEMENT, LLC, Plaintiffs, v. INSYS THERAPEUTICS, INC., MICHAEL L. BABICH, ALEC BURLAKOFF, MICHAEL J. GURRY, RICHARD M. SIMON, SUNRISE LEE, JOSEPH A. ROWAN, STEVE FANTO, MAHMOOD AHMAD, AND JOHN DOES 1-10. Defendants.	PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION September 2017 No. 170602779 **COMPLAINT**

Aetna Inc. and Aetna Health Management, LLC (collectively "Aetna" or "Plaintiffs"), through their attorneys at Lowey Dannenberg P.C. and Elliott Greenleaf, P.C., file this Complaint against Defendants and allege as follows:

I. INTRODUCTION

1. This action arises from a highly successful illegal scheme by Insys Therapeutics, Inc. ("Insys"), the manufacturer of a fentanyl opioid sublingual medication, Subsys, to wrongfully induce healthcare benefit payors like Aetna into paying for expensive, lethally dangerous, addictive, and entirely inappropriate prescriptions for Subsys.

2. Subsys, if properly prescribed, it is to be used for opioid tolerant patients with serious breakthrough pain caused by cancer. Payors like Aetna do not authorize benefit coverage payment for Subsys that is prescribed for any other use.

3. This extremely narrow market, estimated to be one to two million patients in the United States, was the first limitation Insys faced in selling Subsys, which was its only product line and sole source of revenue at the time. The second problem was that payors like Aetna were, in making proper coverage decisions, effectively screening out improper, non-covered Subsys prescriptions and were declining to authorize coverage for roughly 70% of all prior authorization requests when Subsys was first released for sale.

4. Insys cynically gamed around these obstacles and turned Subsys into a billion-dollar drug through a scheme that induced doctors to prescribe Subsys to often vulnerable and unsuspecting patients who never should have received such a dangerous and expensive drug.

5. To monetize wholly inappropriate and lethally dangerous "off-label" Subsys prescription, Insys needed to induce or trick payors like Aetna to pay for them. Insys solved this problem by creating an in-house "prior authorization department" ("PAD") whose entire existence was dedicated to wrongfully induce authorization for payments. The venal methods employed by Insys PAD were shocking. These employees impersonated physicians' medical office staff, used fake names and spoofed fake area codes, and invented cancer diagnoses in order to induce or defraud Aetna by securing unjustified prior authorization for coverage of Subsys.

6. For a time, based on monies improperly received from this scheme, Insys' revenues soared, paid for by payors like Aetna and government health programs like Medicare.

7. Recently, however, the vast scope of Insys' avaricious scheme has come to light. Its senior officers, executives, sales staff, and prior authorization staff have either pleaded guilty or have been indicted for fraud and violation of anti-kickback statutes. The doctors and practitioners Insys bribed to prescribe Subsys off-label have been sanctioned, convicted or are under current criminal investigation, and the families of patients who have died due to Insys' misconduct are seeking redress in court.

8. The foregoing allegations establish that Defendants entered into a years-long pattern of tortious misconduct, insurance fraud, negligent misrepresentation, negligence, and common law fraud, and were unjustly enriched at Plaintiffs' expense in this Judicial District during the period from January 4, 2012, which is the date that Subsys was approved for its specific use in treating opioid-tolerant patients experiencing cancer-related breakthrough pain, through the time when Defendants' unlawful conduct ceased (the "Relevant Period").

9. As detailed in the U.S. Senate Committee on Homeland Security and Governmental Affairs, Ranking Member's Office's recently released report "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," Insys knew about its problematic prior authorization practices and that it "lacked formal policies or monitoring procedures to ensure proper communication between Insys employees and healthcare professionals" but failed to implement "sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices."[1]

[1] U.S. Senate, Committee on Homeland Security & Governmental Affairs, *Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, 4 (Sept. 6, 2017), available at https://www.hsgac.senate.gov/media/minority-media/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics- (last visited Sept. 7, 2017); attached as "Exhibit A."

10. Plaintiffs bring this action to recover for the damages sustained when Insys defrauded Aetna into paying millions of dollars for Subsys prescribed for improper off-label uses.

II. PARTIES

11. Plaintiff Aetna Inc. is a Pennsylvania corporation that maintains its principal place of business in Hartford, Connecticut. Aetna Inc. and its subsidiaries and affiliates are managed care organizations which provide health payment benefits to more than 13 million people in virtually every state and territory of the United States.

12. Aetna Health Management, LLC ("AHM") is a Delaware limited liability company. AHM is a subsidiary of Aetna. AHM develops, operates, and markets group health insurance products, including Medicare Plans. AHM provides administrative services and resources and pays claims and benefits incurred by Aetna members. AHM provides pharmacy benefit management services, including direct reimbursement of pharmacy claims to pharmacy providers; customer and provider services; and development, installation, and implementation of a medication formulary. AHM manages the formularies for Aetna's different plans and develops, negotiates, and arranges for manufacturers' rebate arrangements with the pharmaceutical industry. AHM is responsible for developing and operating a pharmacy precertification unit.

13. Between April 2012 until the present, Aetna paid tens of millions of dollars for inappropriate off-label prescriptions of Subsys for Aetna members in nearly every state in the United States, including the Commonwealth of Pennsylvania and the City of Philadelphia.

14. Defendant Insys Therapeutics, Inc. ("Insys") is a corporation organized under the laws of the state of Delaware and is headquartered in Chandler, Arizona. Insys manufactured the

drug Subsys, which it distributed, marketed and sold Aetna's members, and contracted physicians and healthcare providers throughout the United States, including in the Commonwealth of Pennsylvania and the First Judicial District.

15. Michael L. Babich ("Babich") was at relevant times the President and Chief Executive Officer ("CEO") of Insys. As President and CEO of Insys, Babich was responsible for managing the development, promotion, distribution, and sale of Subsys. Babich resided in Scottsdale, Arizona.

16. Alec Burlakoff ("Burlakoff") held executive management positions at Insys at relevant times including Regional Sales Manager for the Southeast Region and Vice President of Sales. Burlakoff resided in Charlotte, North Carolina.

17. Michael J. Gurry ("Gurry") held executive management positions at Insys at relevant times including Vice President of Managed Markets. Gurry resided in Scottsdale, Arizona.

18. Richard M. Simon ("Simon") held executive management positions at Insys at relevant times including Regional Sales Manager for the Central Region and National Director of Sales. Simon resided in Seal Beach, California.

19. Sunrise Lee ("Lee") held executive management positions at Insys at relevant times including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region. Lee resided in Byron Center, Michigan.

20. Joseph A. Rowan ("Rowan") held executive management positions at Insys at relevant times including Regional Sales Manager for the Southeast Region and Regional Director for the East Region. Rowan resided in Panama City, Florida.

21. Defendants Babich, Burlakoff, Gurry, Simon, Lee, and Rowan are collectively referred to as the "Insys Executive Defendants." The Insys Executive Defendants and Insys are collectively referred to as the "Insys Defendants."

22. The Insys Executive Defendants acted on behalf of Insys when they took the actions described in this Complaint because they knew and intended that Insys would be the primary beneficiary of the conspiracy to defraud Aetna.

23. The Insys Executive Defendants were acting within the scope of their employment when they took the actions described in this Complaint because the purpose of their conspiracy was to (1) increase the number of Subsys prescriptions, and (2) defraud payors including Aetna into paying for these prescriptions under false pretenses.

24. Dr. Steve Fanto ("Dr. Fanto") is a pain management doctor in Scottsdale, Arizona who improperly prescribed Subsys to Aetna members during the Relevant Period.

25. Dr. Mahmood Ahmad ("Dr. Ahmad") is a pain management doctor in Anchorage, Alaska who improperly prescribed Subsys to Aetna members during the Relevant Period.

26. Dr. Fanto and Dr. Ahmad are collectively referred to as the "Speaker Defendants." The Speaker Defendants are licensed medical practitioners registered with the Drug Enforcement Administration ("DEA") and able to prescribe opioids in the course of their professional practice only for an indicated and legitimate medical purpose. As prescribers of Transmucosal Immediate-Release Fentanyl ("TIRF") drugs, the Speaker Defendants are also required to be enrolled in the TIRF Risk Evaluation and Mitigation Strategy ("REMS") Access program ("the Program").

27. John Does 1 through 10 are licensed medical practitioners who were registered with the Drug Enforcement Administration ("DEA") and are believed to be able to prescribe

opioids in the course of their professional practice only for an indicated and legitimate medical purpose, were enrolled in the Program, and participated in the conspiracy by improperly prescribing Subsys to Aetna members.

28. These prescribers had a legal and a fiduciary duty to their patients to refrain from accepting or agreeing to accept bribes and kickbacks in exchange for any drug. At relevant times, John Does 1-10 engaged in various illegal activities with Defendants and other unknown persons and entities to defraud payors, including Aetna, as described in this Complaint.

29. The Speaker and Insys Defendants knew or should have known that Aetna only provided healthcare benefits for Subsys for its FDA approved use and conditions.

30. The Speaker and Insys Defendants knew or should have known that Aetna would rely upon their misrepresentations, omissions and falsehoods in paying for benefits on behalf of members that were not properly payable.

31. The Speaker and Insys Defendants knew or should have known that Aetna would rely upon their misrepresentations, material omissions and falsehoods.

III. INSYS, JURISDICTION AND VENUE

32. This Court has personal jurisdiction over Defendants because Defendants carried on a continuous and systematic part of their general business within this Judicial District and the Commonwealth of Pennsylvania and caused harm or tortious injury in this Judicial District within the Commonwealth. This Court may exercise personal jurisdiction over Defendants consistent with due process and under 42 Pa.C.S.A. § 5301(a)(2), 42 Pa.C.S.A. § 5322, and the Fourteenth Amendment to the Constitution of the United States. Moreover, Defendants have transacted the business that is the subject matter of this lawsuit in this Judicial District.

33. Plaintiffs suffered injury in this Judicial District because Defendants fraudulently and/or negligently induced and caused Plaintiffs to pay monies for off-label, non-covered healthcare benefits based upon prescriptions of Subsys and the acts and omissions of Insys in this Judicial District, as more particularly alleged in Part V, *supra*, under the false pretense that members were entitled for coverage Subsys based upon allegedly by experiencing breakthrough cancer pain.

34. Unfortunately, Defendants also bribed prescribers throughout the United States, including in Pennsylvania, with improper inducements, phony speaking fees and illegal kickbacks for prescribing off-label Subsys in Pennsylvania, as more particularly alleged in Part V, *supra*, which caused Aetna to be harmed when it reimbursed fraudulent prescriptions for Subsys written by these providers.

35. Insys distributed "opt-in" forms, as more particularly alleged in Part V, *supra*, to medical offices throughout the United States, including the Commonwealth, that authorized the patient's prescriber to send the patient's medical information directly to the PAD. PAD staff solicited the information required to fill out the forms from prescribers throughout the United States, including the Commonwealth. Completed opt-in forms concerning patient diagnoses and medical records, including falsified medical records and descriptions of medical records, were faxed or emailed to the PAD from the offices of practitioners located throughout the United States, including the Commonwealth.

36. Plaintiffs' injuries arose from these activities because these activities were the means through which Defendants' conspired to defraud Plaintiffs into paying for non-covered off-label Subsys prescriptions.

37. Venue is proper here under Pa.R.C.P. 1006 and 2179 because transactions or occurrences out of which the causes of action arise took place in Philadelphia County. Defendants have transacted business that is the subject matter of this lawsuit in this Judicial District; Defendants prepared and submitted false medical records, statements about patient medical records, and bribed providers to over prescribe Subsys for dangerous and improper uses in and from this Judicial District; Defendants caused Subsys to be dispensed under fraudulent pretenses to patients residing in this Judicial District; and Defendants targeted Aetna and its subsidiaries as a victim of the fraudulent scheme described in this Complaint.

IV. BACKGROUND

A. Subsys

38. Subsys is a proprietary, single-use product that rapidly delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue. Fentanyl, which is 50 times more potent than heroin, is a Schedule II substance under the Controlled Substances Act. Subsys is manufactured and sold exclusively by Insys. Insys received approval for Subsys by the Food and Drug Administration ("the FDA") in January 2012 to treat breakthrough cancer pain in opioid-tolerant patients and commercially launched Subsys in March 2012. Subsys is not approved for any other use.

39. Subsys is offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages, but the FDA requires the prescriber to use the lowest possible dose of Subsys that adequately treats a patient's cancer symptoms through "titration," where the doctor initially prescribes 100 micrograms and slowly increases to higher dosages at a specified schedule.

40. Subsys comes in a 30 spray unit package. An example 2014 pricing schedule for a single 30 spray unit package by strength is set forth in the following chart:

Strength (mcg)	Price Per 30 Unit Package
100	$907
200	$1,276
400	$1,806
600	$2,343
800	$2,885
1200	$2,399
1600	$3,164

41. Due to the substantial risk for abuse, addiction, and overdose, Subsys is in a class of drugs known as Transmucosal Immediate-Release Fentanyl (TIRF). Subsys and other TIRF drugs are available only through a restricted program required by the FDA called the Transmucosal Immediate-Release Fentanyl Risk Evaluation and Mitigation Strategy (the "TIRF REMS Access Program"). Under the TIRF REMS Access Program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program, and must comply with its requirements.

B. Fentanyl and the National Opioid Epidemic

42. The United States is suffering from a grave public health crisis: an opioid overdose epidemic. The Centers for Disease Control and Prevention ("CDC") reported that "[o]pioids (including prescription opioids and heroin) killed more than 33,000 people in 2015, more than any year on record. Nearly half of all opioid overdose deaths involve a **prescription opioid**."[2] The CDC reported that since 1999, the number of overdose deaths in the United States

[2] Opioid Overdose, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/index.html (last visited Jul. 11, 2017) (emphasis added).

involving opioids quadrupled.[3] From 2000 to 2015, over half a million people died from drug overdoses, and overdoses from prescription opioids are a driving factor in the fifteen-year increase in opioid overdose deaths.[4]

43. "The opioid epidemic has exacted a staggering human and financial cost in the United States over the past 20 years. Approximately 183,000 Americans died from prescription opioid overdoses between 1999 and 2015, with more than 15,000 Americans dying in 2015 alone."[5]

44. Fentanyl is a fast acting synthetic opioid prescription pain reliever that is fifty times more potent than heroin and one hundred times more potent than morphine.

45. In 2015, there were 6.5 million fentanyl prescriptions dispensed in the United States.[6] According to reports compiled by the Drug Enforcement Administration (the "DEA"), fentanyl-related overdose deaths jumped from around 550 deaths in 2013 to over 2,000 deaths in 2014.[7]

46. In 2014, in Pennsylvania alone, fentanyl overdose is attributed to the death of 400 in Philadelphia and over 2,000 fatal overdoses in Pennsylvania.

47. 50. In Philadelphia, Health Commissioner Thomas said the city is averaging 100 overdose deaths per month in 2017, noting that fentanyl "has thrown gasoline into a fire that was already raging."[8]

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[3] Understanding the Epidemic, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Jul. 11, 2017).

[4] *Id.*

[5] Exhibit A at 1.

[6] Understanding the Epidemic.

[7] *Id.*

[8] Nicole Lewis, Emma Ockerman, Joel Achenbach & Wesley Lowery, *Fentanyl linked to thousands of urban overdose deaths*, WASHINGTON POST (Aug. 15, 2017), available at

48. Like other opioids, the use of fentanyl in any form can lead to severe physical and/or psychological dependence, and may also result in sedation, nausea, vomiting, respiratory depression, circulatory depression, substance abuse and addiction, and/or death.

49. Based upon the inherent dangers and potential for abuse that could lead to severe dependence, the DEA classified fentanyl as a Schedule II narcotic.

C. Schedule II Drugs

50. The drugs and other substances that are considered controlled substances under the Controlled Substances Act (the "CSA"), 21 U.S.C.A. § 801, *et seq.*, are divided into five schedules. Fentanyl is a Schedule II drug, which means that it has been found to have "a high potential for abuse," has a "currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and abuse of the drug "may lead to severe psychological or physical dependence."[9] Examples of Schedule II drugs other than fentanyl include morphine, codeine, opium, methadone, cocaine, and amphetamine. Because Subsys contains fentanyl, Subsys is a Schedule II drug.

51. The DEA is responsible for enforcing the CSA and ensuring that all controlled substance transactions take place within the "closed system" of distribution established by Congress.[10] Within this "closed system," all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and researchers – must be registered with the DEA and maintain strict accounting for all distributions.[11] A prescription for a controlled

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https://www.washingtonpost.com/graphics/2017/national/fentanyl-overdoses/?utm_term=.106519c81c23 (last visited Aug. 25, 2017).

[9] 21 U.S.C.A. § 812(b)(2).

[10] Practitioner's Manual, Drug Enforcement Administration, p. 3 (2006 Ed.), available at https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

[11] *Id.*

substance such as Subsys may be issued only by an individual who is authorized to prescribe controlled substances in the jurisdiction in which the individual is licensed to practice and registered with the DEA.[12] To be valid, a prescription for a controlled substance must be issued by a practitioner acting in the usual course of professional practice.[13] The manner of issuance of prescriptions for controlled substances is also strictly regulated: all prescriptions must be dated as of and signed on the day when issued; all prescriptions must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name and address of the practitioner.[14] For drugs listed in Schedule II, a pharmacist may only dispense directly pursuant to a written prescription signed by the practitioner.[15] The refilling of a prescription for a Schedule II controlled substance is prohibited.[16]

D. The FDA Approval Process

52. To obtain permission to market a drug, the manufacturer must submit a New Drug Application (NDA) to the FDA. The contents of a marketing application vary somewhat depending on the type of application, but generally include:

- Proposed labeling for the product, which includes proposed indications and how the product is to be administered;
- Information about the components, physical characteristics, and/or chemistry of the product;
- Information about how the product will be manufactured;
- Marketing history of the product, if any; and

[12] 21 C.F.R. § 1306.03.
[13] 21 C.F.R. § 1306.04(a).
[14] 21 C.F.R. § 1306.05.
[15] 21 C.F.R. § 1306.11.
[16] 21 C.F.R. § 1306.12.

- Information from all relevant laboratory, animal and clinical studies supporting the approval or clearance of the application.

53. The Food, Drug and Cosmetic Act (the "FDCA") protects the public from drugs that are not proven to be safe and effective. Under the FDCA, a company must specify each intended use of a drug in its application to the FDA. After the FDA approves the drug as safe and effective for a specified use, any promotion by the manufacturer for other uses – known as "off-label" uses – renders the product misbranded. The misbranding of any drug is prohibited by the FDCA. The FDA approval process ensures that pharmaceutical companies market their medications for uses that are proven to be safe and effective.

54. Dr. Margaret Hamburg, Commissioner of the FDA, has said that "the 'off-label' promotion of drugs threatens public health and the role of the FDA, which has served our country well and has protected Americans from unsafe and ineffective drugs."[17]

55. In addition to formal marketing efforts, less conspicuous methods of promoting drugs for off-label uses, are also recognized threats to public health. As Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services explained, "fraudulent marketing of drugs through off-label promotion or kickbacks to prescribers undermines the protections afforded by the drug approval process and medical decision-making." [18]

56. Insys submitted a New Drug Application (NDA) for Subsys to the FDA on March 4, 2011, pursuant to Section 505(b)(2) of the FDCA. The new drug application provided for the use of Subsys for "the management of breakthrough pain in adult cancer patients who are already

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[17] *Allergen Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion of Botox®*, U.S. Dept. of Justice Press Release, Food and Drug Administration, Office of Criminal Investigations (Sept. 1, 2010), https://www.fda.gov/iceci/criminalinvestigations/ucm247741.htm.

[18] *Id.*

receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[19] The FDA approved the application for Subsys for use as recommended in the labeling text. Specifically, the FDA approved indications and usage for Subsys[20] are the following:

> SUBSYS is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
>
> Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, at least 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking SUBSYS.
>
> Limitations of Use:
>
> - Not for use in opioid non-tolerant patients.
> - Not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency room.
> - As a part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access program, SUBSYS may be dispensed only to outpatients enrolled in the program [see Warnings and Precautions (5.7)]. For inpatient administration of SUBSYS (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

The contraindications listed on the FDA approved Subsys label are the following:

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[19] Subsys NDA Approval Letter, FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202788s000ltr.pdf

[20] Subsys prescribing information, http://www.subsys.com/assets/subsys/client_files/files/PrescribingInfo.pdf (last visited June 14, 2017).

- Opioid non-tolerant patients.
- Management of acute or postoperative pain including headache/migraine and dental pain, or in emergency department.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to fentanyl, or components of SUBSYS. [21]

57. The Subsys label is required to have a clearly marked warning section, warning patients of risk of life-threatening respiratory depression, medication errors, and abuse potential (also known as a "black box warning").

58. Section 505-1 of the FDCA authorizes the FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if the FDA determines that such a strategy is necessary. The factors the FDA considers pursuant to Section 505-1(a)(1) when making this determination include the following:

(A) The estimated size of the population likely to use the drug involved;

(B) The seriousness of the disease or condition that is to be treated with the drug;

(C) The expected benefit of the drug with respect to such disease or condition;

(D) The expected or actual duration of treatment with the drug;

(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

[21] *Id.*

59. The FDA determined that a REMS was necessary for Subsys to ensure the benefits of the drug outweigh the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors.[22] In reaching this determination, the FDA considered the following:

- The estimated number of patients in the United States with breakthrough cancer pain is *between 1 to 2 million*. This estimate is based upon the number of patients with cancer in the US (American Cancer Society), the proportion of cancer patients with moderate to severe pain, and the proportion of cancer patients with breakthrough pain.

- *The patients for this product are cancer patients* with pain that cannot be adequately controlled using around-the-clock oral or transdermal opioids alone. Many of these patients have multiple concurrent complications of their underlying disease and therapy.

- The most serious of the known adverse events that are related to the use of fentanyl-containing products include death, respiratory depression, and CNS depression which occur primarily if the product is not used properly. In addition to the aforementioned risks, fentanyl sublingual spray, as other fentanyl-containing products, can have a potential to increase intracranial pressure and induce bradyarrhythmias.[23]

60. As one element of the REMS, the FDA determined that Insys is required to distribute a Medication Guide to patients taking the drug because "Subsys poses a serious and significant public health concern requiring the distribution of a Medication Guide."[24]

61. The FDA also determined that Subsys could be approved "only if elements necessary to assure safe use are required as part of a REMS to mitigate the risks of misuse,

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[22] Subsys NDA Approval Letter, FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202788s000ltr.pdf

[23] Risk Evaluation and Mitigation Strategy (REMS) Memorandum, FDA, Center for Drug Evaluation and Research (Jan. 2, 2011), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000RiskR.pdf

[24] *Id.*

abuse, addiction, overdose, and serious complications due to medication errors that are listed on the labeling" pursuant to section 505-1(f)(1) of FDCA.[25] The FDA stated that "the elements to assure safe use will help assure proper patient selection and dispensing of Subsys."[26]

E. The Program for the Highly-Potent TIRF Class of Fentanyl Substances

62. The FDA's Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation and Mitigation Strategy Program (the "TIRF REMS Program") is an "FDA-required program designed to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines."[27] The purpose of the program is "mitigat[ing] the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines."[28]

63. TIRF medicines are formulations of fentanyl that instantly deliver medicines to their users via the oral mucosa. There are currently six approved TIRF medications, including Subsys.

64. The only approved indication for all TIRF substances, including Subsys, is for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, regular opioid therapy for their underlying persistent cancer pain.

65. The FDA has explained that the indication for TIRF substances is narrow for the following reasons:

> [T]he population identified has a specific need for a treatment to address cancer-associated breakthrough pain, which is characterized by a quick onset, often high severity, and relatively short duration. These formulations of fentanyl are

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[25] Subsys NDA Approval Letter, 3.
[26] *Id.*
[27] TIRF REMS ACCESS PROGRAM, https://www.tirfremsaccess.com/TirfUI/rems/home.action.
[28] *Id.*

> designed to have a rapid rise to [maximum concentration] and a relatively short duration of effect. Fentanyl is a very potent opioid that can cause respiratory depression in microgram quantities. For this reason, the indication also reflects the need for patients to be opioid-tolerant, a physiological state in which patients are more tolerant to the CNS depression and respiratory depression associated with opioids.[29]

66. Because of the "risk for misuse, abuse, addiction, overdose, and serious complications due to mediation errors," TIRF medicines are available only through the TIRF REMS Access program, a restricted distribution program required by the FDA.

67. The TIRF REMS Access Program governs the health care industry's access to TIRF medications. The Program is arranged to ensure informed risk-benefit decisions before initiating treatment and ensure the proper use of TIRF medicines. The TIRF REMS Access Program requires all prescribers, pharmacies, wholesalers, and distributors to enroll in the program before prescribing, purchasing, or dispensing the TIRF medicines. All physicians who seek to prescribe TIRF substances to outpatients must first enroll in the TIRF REMS Access Program. Unless a physician enrolls in this Program, an authorized pharmacy may not fill prescriptions for TIRF medications written by a non-enrolled physician. Furthermore, before a patient can be prescribed a TIRF medicine, he or she must complete and sign a "Patient-Prescriber Agreement Form"[30] along with the prescribing physician. Each of these requirements must be renewed and completed every two years.

68. To enroll in the Program, both prescribers and pharmacies must complete a TIRF REMS Education Program and correctly answer questions concerning the proper indications and

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[29] Subsys, FDA, Division Director's Review and Summary Basis for Approval, 3-4 (Jan. 4, 2012), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000SumR.pdf (last visited Jul. 11, 2017).

[30] TIRF REMS Access Patient-Prescriber Agreement Form, available at https://www.tirfremsaccess.com/TirfUI/rems/pdf/ppaf-form.pdf (last visited Jul. 12, 2017).

dosage for the TIRF medicines. This Education Program relays key safety information essential for minimizing the risks associated with TIRF medicines and makes clear that TIRF medicines are only indicated for the management of breakthrough cancer pain in adult patients with cancer "**who are already receiving and who are tolerant to regular opioid therapy for underlying persistent cancer pain**."[31] Because life-threatening respiratory depression and death could occur at any dose in patients not taking chronic opioids, TIRF medicines have strict contraindications for opioid non-tolerant patients.

69. The Education Program section on proper dosage begins with the requirement that "[p]atients beginning treatment with a TIRF medicine MUST begin with titration from the lowest dose available for that specific product, even if they have taken another TIRF medicine."[32] This section warns that "TIRF medicines are not interchangeable with each other. . . . As a result of these differences, the conversion of a TIRF medicine for any other TIRF medicine may result in fatal overdose."[33] For Subsys, the initial dose is always 100 mcg (unless the patient is being converted from Actiq).[34] The dose adjustment guidance for all TIRF medicines is "[o]nce a successful dose is found, that dose should be prescribed for each subsequent episode of breakthrough cancer pain."[35]

70. The Education Program instructs prescribers to review the product-specific Medication Guide with the patient before initiating treatment with a TIRF medicine. For

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[31] Education Program for Prescribers and Pharmacists, TIRF REMS Access, 3, available at https://www.tirfremsaccess.com/TirfUI/rems/pdf/education-and-ka.pdf (last visited Jul. 12, 2017) (emphasis in original).

[32] *Id.* at 5.

[33] *Id.*

[34] *Id.* at 8.

[35] *Id.* at 6.

effective patient management and follow-up, the Education Program warns that "[a]ll patients treated with opioids require careful monitoring" and instructs to assess for signs of misuse, abuse or addiction at follow-up visits.[36]

71. The Patient-Prescriber Agreement Form that must be signed by the prescriber requires the prescriber to acknowledge that he or she:

a. understands that "TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain;"

b. understands that "TIRF medicines are contraindicated for use in opioid non-tolerant patients" and that "fatal overdose can occur at any dose;"

c. understands that "patients considered opioid-tolerant are those taking at least: 60 mg oral morphine/day; 25 micrograms transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; or an equianalgesic dose of another opioid for one week or longer";

d. has provided to and reviewed with the patient or caregiver the Medication Guide for the TIRF medicine intended to prescribe;

e. will provide the Medication Guide for the new TIRF medicine to the patient if the prescriber changes the patient to a different TIRF medicine and review it with the patient;

f. understands that if the prescriber changes the patient to a different TIRF medicine, "the initial dose of that TIRF medicine for all patients is the lowest

[36] *Id.* at 9.

dose, unless individual product labels provide product-specific conversion recommendations";

g. has counseled the patient or caregiver about the risks benefits, and appropriate use of the TIRF medicine.

F. The TIRF REMS Access Program Pharmacy Management System

72. The patient must sign the Patient-Prescriber Agreement and take the prescription for a TIRF medicine to an enrolled pharmacy. The pharmacy will enroll the patient in the TIRF REMS Access program. Prescriptions written by prescribers who are not enrolled in the REMS program will not be authorized by the TIRF REMS Access program, and TIRF medicines will not be dispensed to an outpatient who is not enrolled.

73. For the purpose of the TIRF REMS Access program, the patient's name, address, telephone number, and prescription information make up the patient's "Health Information." The patient's doctors, pharmacists, and healthcare providers may share the patient's health information with the TIRF REMS Access program, and the health information will be kept in a secure database. The TIRF REMS Access program receives, uses, and shares the health information in order to enroll the patient in the TIRF REMS Access program, manage the patient's participation in the TIRF REMS Access program, and contact the patient's healthcare providers to collect health information for the TIRF REMS Access program.

74. All pharmacies are required to be enrolled in the TIRF REMS Access program, complete the TIRF REMS Education Program, and verify patient and prescriber enrollment when processing prescriptions.

75. All TIRF prescriptions must go through an electronic verification system via the pharmacy management system. When a prescription is denied, an appropriately coded message

will be displayed on the pharmacy management system. Each day, wholesalers receive a list of enrollees in the TIRF REMS Access program – including prescribers, pharmacies, and patients. If the prescriber, pharmacy, or patient is not enrolled in the program, the claim will not go through.

76. The goals of the TIRF REMS Access program are to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors by prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients; preventing inappropriate conversion between fentanyl products; preventing accidental exposure to children and others for whom it was not prescribed; and educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

77. This system fails when prescribers enrolled in the TIRF REMS Access program, understanding that only cancer patients should be prescribed Subsys and should be prescribed the lowest dose initially, prescribe Subsys to patients without cancer diagnoses, some with higher initial doses than required, and inappropriately enroll them in the TIRF REMS Access program.

78. Pharmacists enrolled in the program should have also understood that only cancer patients should be prescribed Subsys and should be prescribed the lowest dose initially. Accordingly, discovery will reveal whether the pharmacists who dispensed Subsys inappropriately were complicit in the fraudulent scheme or were also deceived by the Defendants.

G. Aetna's Subsys Precertification Criteria

79. Consistent with the TIRF REMS program, and the closely circumscribed FDA-approved uses of Subsys, Aetna maintains and publishes a prior authorization process to ensure

that it only reimburses member covered benefits for costly, dangerous drugs such as Subsys where the drug is restricted to be prescribed for the FDA-approved use.

80. Aetna uses its Pharmacy Management Precertification Unit (the "PMPU") to confirm coverage applies where Subsys is only being prescribed to treat breakthrough pain in opioid-tolerant cancer patients. Aetna requires its member patients to obtain prior authorization from the PMPU before filling each prescription for Subsys to ensure that Subsys is not being prescribed to the wrong patients or for the wrong conditions.

81. Aetna classified Subsys as a Formulary Excluded drug and requires Precertification, Quantity Limits, and Step-Therapy (explained below), and requires a Medical Exception. Medical Exception means the member or treating physician or health care professional must obtain a medical exception from Aetna in order for the medication to be eligible for coverage. It also applies to Step-Therapy drugs in cases where a member's physician believes it is medically necessary for the member to use a step-therapy drug in the first instance without a trial of the prerequisite alternative drug(s). Medical Exception may also apply if Precertification applies to a drug and if it is medically necessary for a member to be treated with a medication(s) subject to precertification that falls outside those precertification criteria requirements. The member or the member's treating physician may contact the PMPU to request additional review for medical necessity.

82. At all relevant times, Insys knew or should have known Aetna's policies regulating the approval for member covered benefits relating to TIRF drugs, including Subsys.

83. Subsys is subject to precertification. Aetna considers Subsys to be medically necessary for those members who meet the following precertification criteria:

- A documented diagnosis of cancer AND concomitant use of long acting opioid therapy;[37] AND
- A documented contraindication or intolerance or allergy or failure of an adequate trial of one week of the preferred generic fentanyl transmucosal lozenge.

84. Subsys is also subject to step-therapy, and patients who are prescribed Subsys must meet the following step-therapy criterion:

> A documented trial of one week of the preferred generic fentanyl transmucosal lozenge. If it is medically necessary for a member to be treated initially with a medication subject to step-therapy, the member, a person appointed to manage the member's care, or the member's treating physician may contact the Aetna Pharmacy Management Precertification Unit to request coverage as a medical exception.

H. The TIRF Market

85. Subsys entered the market in March 2012 as the sixth TIRF medication to be marketed commercially. One of the earlier TIRF drugs to market, Actiq, had already been sold in generic form since 2006.

86. Insys faced many impediments to the success of Subsys due to its limited approved use, including its extremely narrow customer base; having to construct a sales and marketing force from the ground up; being a latecomer to a mature market dominated by larger drug companies; having to comply with the FDA's stringent marketing restrictions and TIRF REMS Access Program requirements; and needing to obtain approval of public and private resources of reimbursement, including health insurers, to subsidize the drug's very high price-tag.

[37] Members who reside in or use California as their contract state and have a terminal illness may also meet the requirements under certain circumstances.

87. Subsys widely succeeded beyond the market's expectations. Since late 2014, Subsys has been the most prescribed TIRF product with 48% market share on a prescription basis.[38]

88. Behind that success is the secret, aggressive, fraudulent, and unlawful marketing to prescribers who did not treat many cancer patients and the payment of higher commissions to Insys sales representatives for selling higher doses of Subsys. Defendants systematically engaged or negligently allowed its employees and or agents to engage in deceptive sales and marketing practices which caused Aetna and its members to pay for Subsys to treat a variety of claimed illnesses and symptoms for which Subsys had not received approval from the FDA and for which the drug was not safe or medically appropriate. Defendants' deceptive conduct targeted Aetna and other payors.

89. Defendants' deceptive marketing and sales practices included: (a) directly marketing to and soliciting prescribers to prescribe Subsys for a variety of unapproved off-label uses not approved by the FDA; (b) misrepresenting the safety and medical efficacy of Subsys for off-label uses; (c) defrauding payors by disguising the identity and location of certain Defendants' employees; (d) instructing, scripting and coaching certain Defendants' employees to lie or mislead about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication; (e) improperly and secretly compensating physicians for prescribing Subsys for off-label uses; and (f) causing doctors to submit claim forms to Aetna containing misinformation and omissions regarding Subsys.

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[38] Investors overview, Insys, http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-irhome (last visited Jul. 12, 2017).

90. Defendants' deceptive practices caused Aetna to pay for claims for Subsys to treat a variety of off-label conditions for which the drug was not properly the subject of covered reimbursement and was neither safe or medically appropriate.

I. Government Enforcement Actions and Investigations

91. Defendants' wrongful scheme has drawn numerous governmental actions and investigations.

92. The United States commenced a criminal action against Defendants Babich, Burlakoff, Gurry, Simon, Lee, and Rowan, who were arrested on December 8, 2016 on charges they led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe Subsys and defraud healthcare payors. *U.S. v. Babich, et al.*, No. 1:16-cr-10343 (D. Mass.). The indictment alleges that practitioners wrote large numbers of prescriptions for Subsys in exchange for bribes and kickbacks and that the former executives conspired to mislead and defraud health insurance providers who would not approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up the "reimbursement unit"[39] which was dedicated to obtaining prior authorization directly from payors and pharmacy benefit managers.

93. The United States also commenced a criminal action against a former manager at Insys, Elizabeth Gurrieri, who pleaded guilty on June 19, 2017. *U.S. v. Gurrieri*, No. 1:17-cr-10083 (D. Mass.) Gurrieri admitted that she helped lead the nationwide scheme to defraud insurance companies by directing employees at the Insys Reimbursement Center to lie to insurers, defrauding them into paying for Subsys. Gurrieri admitted that she and her co-

[39] The "reimbursement unit" and the "prior authorization department" are used interchangeably throughout this Complaint.

conspirators used a call center to contact the insurance companies to provide prior authorizations, often under false pretenses for patients not suffering from cancer. The Insys employees sometimes disguised where they were calling from, leading payors to believe that they were speaking directly with a doctor's office, rather than with the drug maker that stood to profit.

94. U.S. Senator Claire McCaskill, Ranking Member of the U.S. Senate Committee on Homeland Security and Governmental Affairs ("HSGAC"), led an investigation into the soaring rate of opioid deaths in the United States and sent letters to five major opioid manufacturers, including Insys, requesting documents related to the sales, marketing, and educational strategies employed to promote opioid use on March 28, 2017. The HSGAC released its report on Insys on September 6, 2017, entitled "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization."[40] The report revealed an internal Insys presentation dated 2012 and entitled "2013 SUBSYS Brand Plan," where Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[41] The HSGAC reported an internal Insys document that showed that Insys lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies."[42] The HSGAC reviewed the case of Subsys patient Sarah Fuller, who died of allegedly improper and excessive Subsys use, and reported an audio recording that revealed that "an Insys employee misled representatives of Envision Pharmaceutical Services to obtain approval for her prescription."[43]

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[40] Exhibit A.

[41] *Id.* at 5.

[42] *Id.* at 1.

[43] *Id.* at 1-2; full audio of the call between the Insys employee and pharmacy benefit manager representatives related to a Subsys prescription for Sarah Fuller is available at https://www.hsgac.senate.gov/media/minority-media/breaking-mccaskill-opioid-investigation-

95. When releasing the report, Senator McCaskill said, "[t]here is extensive evidence that Insys aggressively pressured its employees and the entire medical system to increase the use of a fentanyl product during a national epidemic that was taking the lives of tens of thousands of Americans a year in order to make more money—it's hard to imagine anything more despicable. . . . Their attempts to manipulate the prescription approval process for this drug appear to have been systemic, and anyone responsible for this manipulation deserves to be prosecuted."[44]

96. The Oregon Attorney General served a Notice of Unlawful Trade Practices on Insys on July 10, 2015, and on August 5, 2015 reached a $1.1 million settlement with Insys. Oregon was the first state in the country to allege that Insys promoted Subsys "off-label" for non-cancer pain such as back pain and neck pain, uses for which Subsys is not safe, not approved, and not eligible for reimbursement by either public or private payors. Oregon outlined allegations in its Notice that Insys unconscionably targeted "problem doctors" who mis-prescribed opiates with aggressive Subsys promotion and that Insys facilitated prescribing of Subsys for contraindicated uses.

97. The New Hampshire Attorney General brought an enforcement action under the state's Consumer Protection Act against Insys. On or about December 8, 2015, New Hampshire issued a subpoena to Insys for an investigation into the commercial practices of Insys regarding marketing Subsys in New Hampshire. On January 18, 2016, New Hampshire Attorney General

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releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics- (last visited Sept. 7, 2017).

[44] *BREAKING: McCaskill Opioid Investigation Releases First Report Detailing Systemic Manipulation of Prior Authorization Process by Insys Therapeutics*, U.S. Senate, Committee on Homeland Security & Governmental Affairs (Sept. 6, 2017), https://www.hsgac.senate.gov/media/minority-media/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics- (last visited Sept. 7, 2017).

accepted the Assurance of Discontinuance, under which Insys has paid the State of New Hampshire $2,900,000 for its collective violations of the Consumer Protection Act. Insys also agreed to make a direct payment of $500,000 to the New Hampshire Charitable Foundation to be used to prevent or remediate problems related to abuse, misuse, or mis-prescribing of opioid drugs in New Hampshire.

98. The Illinois Attorney General filed a state consumer fraud complaint on August 25, 2016, seeking an injunction to stop Insys from doing business in the state for its off-label promotion of Subsys. *Illinois v. Insys Therapeutics, Inc.,* No. 2016-CH-11216 (Cook Co.) (the "Illinois Action"). Illinois sought a declaration that Insys violated Section 2 of the Illinois Consumer Fraud Act by engaging in unlawful acts and practices and an injunction preventing Insys from engaging in unfair and/or deceptive sales practices.[45] Illinois alleged that from January 2012 through March 2015, Insys sales representatives aggressively targeted high-volume opioid drug prescribers "without regard to the suitability of the patient population for the approved use of Subsys." Illinois alleged that Insys did so while misrepresenting to physicians and patients the approved use and dosage parameters for Subsys.

99. On August 18, 2017, Illinois announced a settlement of $4.5 million with Insys. The settlement requires Insys to comply with the Illinois Consumer Fraud Act, the Illinois and federal Food, Drug, and Cosmetics Acts, and the Federal Anti-Kickback Statute. The settlement also requires Insys to:

- "Create an Opioid Abuse Detection Program to identify prescribers who are abusing or aiding in the abuse of opioids;

[45] *See* 815 Ill. Comp. Stat. 505/2.

- Restrict promoting Subsys only to oncologists and prescribers who have affirmatively stated they currently treat or are likely to treat patients with cancer pain;
- Prevent Insys employees from communicating with an Illinois patient's insurance company regarding prior authorization of an opioid;
- Limit the number of times a prescriber can host an Insys speaker program and the number of times a prescriber can attend an Insys speaker program; and
- Prohibit sales representatives from communicating about a particular patient with a prescriber, initiating direct communication with a patient, or having access to a patient's medical records."[46]

100. On August 22, 2017, Insys issued a statement regarding the settlement with Illinois, that the settlement "reflects [Insys'] firm commitment to take responsibility for actions by [Insys'] former employees."[47]

101. The Arizona Attorney General filed an Arizona Consumer Fraud lawsuit against Insys, Alec Burlakoff, Elizabeth Gurrieri, and three Arizona doctors, including Steve Fanto, on August 31, 2017.[48] Arizona alleges that Insys engaged in a fraudulent marketing scheme designed to increase the sales of Subsys and violated the Arizona Consumer Fraud Act by

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[46] *Madigan Reaches $4.5 [Million] Settlement With Drugmaker Insys for Deceptively Selling & Marketing Highly Addictive Opioid Painkiller*, Illinois Attorney General (Aug. 18, 2017), http://www.illinoisattorneygeneral.gov/pressroom/2017_08/20170818.html (last visited Aug. 25, 2017).

[47] *Insys Addresses Questions Raised by Illinois Settlement*, News Release, Insys (Aug. 22, 2017), http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-newsArticle&ID=2294960 (last visited Aug. 25, 2017).

[48] *Arizona v. Insys Therapeutics, et al.* (Ariz. Sup. Ct., Maricopa Co.), available at https://www.azag.gov/sites/default/files/sites/all/docs/press-release/press-release-files/2017_Files/complaints/Insys_Complaint_8_30_17.pdf (last visited Sept. 7, 2017).

providing insurers with false and misleading information to obtain prior authorization for Subsys prescriptions for patients. Arizona alleges that Insys employees were instructed to mislead insurers into believing that patients who were prescribed Subsys had cancer, when in fact they did not. Arizona alleges that the three doctors collected sham educational "speaker fees" in exchange for writing prescriptions for Subsys. Arizona alleges that more than $33 million, or 64 percent, of Subsys sales in Arizona came from prescriptions written by the three doctors between March 2012 to April 2017. This litigation is ongoing.

V. THE FRAUDULENT SCHEME

102. Insys only sold one product during the Relevant Period: Subsys. Nevertheless, Insys' valuation soared throughout the Relevant Period because Insys turned Subsys into a billion dollar drug by *inter alia*: (1) paying bribes and kickbacks to providers so they would prescribe Subsys off-label; (2) training Insys staff to pose as providers and call Aetna's PMPU staff to make knowingly false misrepresentations about patient medical records; (3) encouraging Insys staff to execute fraudulent and deceptive tactics designed to trick Aetna into paying for off-label prescriptions of Subsys; and (4) inducing prescribers to provide their patient medical charts and Aetna member information to facilitate Insys' scheme and to induce payment from Aetna

103. The success of Subsys seemed highly unlikely when Subsys was first approved for sale. In 2012, when Insys was just launching its "Speaker Program" and "Prior Authorization Department" or "PAD" (described below), sales of Subsys were only $14.3 million.

104. The low number of eligible patients, estimated at one to two million at most, was a substantial headwind that seemed to be an unavoidable constraint on the market potential for Subsys.

105. The drag on revenue caused by the low number of eligible patients was compounded by the fact that payors like Aetna took care to screen out off-label uses of TIRF drugs like Subsys. In November 2012, payors like Aetna were only approving between 30 and 33 percent of prescriptions for Subsys because they had procedures in place to enable them to screen for and deny reimbursement for improper and off-label uses, as described in Part IV, *supra.*

106. Specifically, Aetna required a medical diagnosis of cancer before authorizing reimbursement for Subsys and would not pay for expensive, potentially lethal pain drugs like Subsys until the patient had tried and failed other appropriate, effective and less costly medications.

107. Few would have predicted that by 2013, Insys' fortunes had become the darling of stock-pickers and market analysts. After Insys implemented the fraudulent scheme described in this Complaint, sales increased more than 700% in 2013, and exceeded more than $300 million by 2014. In all, Insys sold more than $1 billion worth of Subsys during the Relevant Period, mostly for off-label use in non-cancer patients. These tremendous profits came at the expense of payors like Aetna.

108. Though many patients suffered tragically as a result of Insys' actions, it was payors like Aetna and the plans it administered who bore the brunt of the financial costs of Defendants' scheme because they were defrauded into reimbursing millions of dollars in unnecessary, unapproved, off-label prescriptions that would have never been approved but for Insys' course of fraudulent conduct.

109. Insys senior executives concocted a two-pronged fraudulent scheme that would send Insys' revenues soaring into the hundreds of millions of dollars annually at the expense of

payors like Aetna in order to overcome Insys' twin revenue "problems"—that Subsys was only approved for the one to two million cancer patients with breakthrough pain and the fact that insurers had procedures in place to avoid paying for improper off-label uses of Subsys.

110. The two-pronged fraudulent scheme that Insys developed involved a multi-faceted, complex, and hugely profitable effort to defraud and induce Aetna into reimbursing wrongly-prescribed Subsys through (1) paying bribes and kickbacks to providers so they would prescribe Subsys off-label; (2) training Insys staff to pose as providers' staff and call Aetna's PMPU to make knowingly false misrepresentations and omit material information about patient medical records, (3) encouraging Insys staff to execute fraudulent and deceptive tactics designed to trick or mislead Aetna into paying for higher doses and off-label prescriptions of Subsys, and (4) inducing prescribers to provide confidential Aetna member information to facilitate Insys' scheme and to induce payment from Aetna.

111. Prong One: Insys developed a "Prior Authorization Department," or "PAD," to have its employees or agents pose as medical office staff and defraud insurers into believing that patients had breakthrough cancer pain. The goal of this prong was to increase the percentage of prior authorizations so that each new off-label prescription for Subsys would have a greater chance of being approved for reimbursement. Through Insys' use of Aetna members' confidential information provided to Insys by prescribers, Insys, through its PAD, exploited, misrepresented or omitted information Aetna would have relied upon to properly authorize coverage and reimbursement for Subsys.

112. Prong Two: Insys overhauled its sales department to focus on bribing and offering kickbacks to prescribers through a sham "Speaker Program," which paid them to overprescribe off-label Subsys to Aetna members in a manner inconsistent with those members' medical

conditions, and at times, in improperly high dosages. The goal of prong two was to generate prescriptions to send to the PAD, who turned these off-label prescriptions into pre-authorized cash reimbursements from insurers.

A. Prong One: The "Prior Authorization Department" Systematically Defrauded Aetna

113. Beginning in or around late 2012, Babich and Gurry tracked information regarding prior authorizations and hired a prior authorization specialist ("PA Specialist"), Gurrieri. The information gathered demonstrated that only 30 to 33 percent of Subsys prescriptions were approved by payors and pharmacy benefit managers, like Aetna.

114. Babich and Gurry directed the PA specialist to seek prior authorizations directly from payors on behalf of patients from select practitioners as part of a pilot program. The prior authorization rate for prescriptions handled by the PA specialist was 46 percent.

115. Based on the pilot program, Babich and Gurry created an Insys-based unit dedicated to obtaining prior authorizations directly from health insurers and pharmacy benefit managers (the prior authorization department or "PAD").

116. PAD staff handled prior authorization requests for patients and were provided with instructions on fraudulent ways to deceive payors into prior authorization for coverage for their members for Subsys for off-label use.

1. The "Opt-In Forms"

117. To enable PAD staff to receive patient medical records, Insys distributed "opt-in" forms to medical offices that authorized the patient's prescriber to send the patient's medical information directly to the PAD. Practitioners using the PAD were required to fill out the opt-in forms, and Babich, Burlakoff, Gurry, Simon, Lee, and Rowan directed PAD staff to obtain and assist practitioners in obtaining the information required to fill out the forms, including, at times,

the patients' medical records. Completed forms were faxed or emailed to the PAD from the offices of practitioners located throughout the United States, including Pennsylvania.

118. The opt-in forms contained confidential patient information such as name and date of birth, payor information, prescriber information, pharmacy information, and the purported medical diagnosis or diagnoses for which Subsys had been prescribed. Opt-In forms were used by PAD staff when communicating with insurers, and the PAD, in turn, became the entity that sought prior authorization directly from the payor.

119. From there, PAD staff executed the next part of the plan—defraud payors into issuing prior authorization and paying for off-label Subsys prescriptions.

2. Insys PAD Used "the Spiel" and Other Fraudulent Tactics

120. In each case, PAD staff impersonated personnel working at the patient's doctor's office by giving misleading or false information and using a system that disguised the area code of the PAD facility, which was located near Insys' headquarters in Chandler, Arizona.

121. Insys PAD management developed a "script" that was designed to mislead and conflate cancer-related breakthrough pain, for which Subsys is approved, and non-cancer breakthrough pain, for which Subsys is not approved and for which Aetna does not authorize coverage reimbursement.

122. The script, also known as "the spiel," was carefully calibrated to mislead agents of payors regarding the patient's medical conditions. For example, one version of the spiel read as follows:

> The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).

123. The spiel falsely implied that the physician was treating the patient for cancer by omitting the word "cancer" from the second sentence in the script.

124. Aetna was victimized by the spiel on numerous occasions. For example, on one occasion, an Insys PAD employee called Aetna's PMPU to request approval for a member's Subsys prescription, falsely introducing himself as "Sam from the doctor's office." When the PMPU employee asked what kind of cancer the patient had, Sam replied that he did not have that information but only knew what it was being used for. When the Aetna employee asked if it was for "breakthrough cancer pain," Sam falsely replied "yeah, for the breakthrough pain."

125. In addition to the spiel, PAD staff resorted to a host of other misleading and fraudulent tactics, including falsely listing diagnoses for conditions that were not actually experienced by the patient in question and were never identified by a doctor. For example, Babich and Gurry learned that insurers were more willing to grant prior authorization to patients diagnosed with dysphagia or difficulty swallowing, a common side effect of cancer treatment. Gurry and others, including Gurrieri who was promoted to manager of the PAD, instructed PAD staff to add the dysphagia diagnosis regardless of whether the patient had in fact difficulty swallowing. Gurrieri instructed PAD staff to "put dysphagia on every single authorization."

126. When a junior PAD staff member asked Gurrieri whether a patient in fact had experienced difficulty swallowing, Gurrieri replied "no, but we have to say that. That's what we have to do to get it approved [by the insurance company] or else they won't approve it."

127. Aetna was victimized by Insys' institutionalized practice of purposefully and improperly impersonating employees at the patient's doctor's office and falsely and misleadingly claiming that a patient suffered from, for example, dysphagia, which implied that the patient was being treated for cancer. On one occasion, PAD staff called Aetna's PMPU and claimed that a

patient had been diagnosed with "Breakthrough Cancer; Dysphagia." However, a subsequent review revealed that the patient did not suffer from either cancer or dysphagia, and Insys had represented these false diagnoses to defraud Aetna into paying for the member's Subsys prescription.

128. In addition to falsely representing dysphagia as a symptom, PAD staff also represented to Aetna "neoplasm-related pain" to falsely imply that the member was suffering from cancer pain. A "neoplasm" is a medical term for a tumorous growth.

129. For example, Aetna determined that one patient of a "speaker," *see* Part V.B., *supra*, had been prescribed Subsys even though the patient did not suffer from cancer. Aetna denied the prior authorization in accordance with its policies and the FDA guidelines.

130. However, the patient's doctor, aided by PAD staff, appealed the coverage decision, misleadingly adding that the patient suffered from "neoplasm-related pain," implicitly suggesting, falsely, that the patient suffered from severe pain caused by a cancerous tumor.

131. The Aetna employee handling the appeal was unable to reach the provider to clarify the nature of the neoplasm and inquire into whether it was cancerous despite repeated attempts. The employee noted that the patient had a diagnosis, which later proved to be false, of "breakthrough cancer pain" in his medical records from a year earlier, and gave the prior authorization.

132. The episode led to Aetna paying for thousands of dollars' worth of Subsys under false pretenses.

133. PAD staff were also trained, allowed or encouraged to lie about cancer diagnoses to improperly expand the number of patients that were eligible for Subsys reimbursements. In patients that had any form of cancer diagnosis ever in their medical history, PAD staff were

ordered that "if there was any history of cancer to give the breakthrough cancer pain code" even where the patient in question had recovered from the cancer episode years earlier.

134. Aetna was victimized by this pattern of negligence and fraudulent practice. For example, on one occasion, a patient who had been diagnosed with melanoma but had been cancer-free since a successful surgery in 2003 was falsely listed by Insys as suffering from "skin (melanoma) cancer pain" in 2015. Thus, Insys falsely represented that patients who had been cancer-free for years were currently experiencing cancer pain to repeatedly defraud Aetna into reimbursing for Subsys prescriptions.

135. For patients who did not have a diagnosis of cancer in their medical histories, PAD staff mislead or simply lied and told insurers that the patient had been diagnosed with cancer by putting in a "cancer code," a medical diagnostic code that designates the patient as having a form of cancer. As Gurrieri put it, "I need you guys to do whatever you have to do. If you have to give them the cancer code, give it to them to get it approved, because it's a new script. Who wants it?"

136. This tactic, like the others used by the PAD, was effective in part because it appeared that the phone calls and medical records were coming from the provider's office. On other occasions, PAD staff would send Aetna prior authorization forms that falsely listed "Diagnosis: Breakthrough cancer pain," for patients who had never been diagnosed with cancer.

137. Aetna was victimized by these tactics on multiple occasions. For example, in 2015, a patient obtained prior authorization for Subsys based on a diagnosis of "cancer-pain." In October 2015, Aetna called the doctor's office to confirm whether the patient was suffering from cancer, and the office confirmed that the patient did not have a cancer diagnosis.

138. Aetna revoked the prior authorization upon learning the patient's true diagnosis, but not before it had already paid for multiple doses of Subsys based upon Defendants' misconduct under the false belief that the patient was suffering from cancer pain.

139. Other reviews confirmed that Insys targeted Aetna with its scheme to obtain fraudulent prior authorizations for Subsys by falsely claiming that patients had cancer pain. In one case from October 2015, an Insys employee named "Sheri" claimed to work at a patient's doctor's office. When the Aetna staff member asked "Sheri" what kind of cancer the patient had, "Sheri" said "Breast Cancer, the [diagnostic code] is D50.919." However, when the Aetna employee followed up with the patient's doctor's office, the employee learned that the patient was suffering from back pain and did not actually have cancer.

140. PAD staff falsely represented that patients had cancer on multiple other occasions. A review uncovered at least 28 false cancer diagnoses in November 2015 alone. Aetna revoked the prior authorizations for these patients, but not before it had already paid thousands of dollars for Subsys based on PAD's fraudulent diagnoses of cancer.

141. On yet another occasion in August 2016, a PAD staff member who gave her name as "Gloria" called Aetna to obtain prior authorization. When Aetna asked for the patient's medical records, "Gloria" said she would call back. "Gloria" called back and claimed that she had spoken with the doctor's office, who had confirmed that the patient was suffering from "breakthrough cancer pain."

142. Due to "Gloria's" misleading, false, and fraudulent statements, the prior authorization was granted.

143. A subsequent follow-up revealed that "Gloria" had been lying all along and the patient had not been diagnosed with cancer.

144. Aetna conducted a review in the fall of 2015, which revealed that the majority of Aetna members who had received prior authorization for Subsys did not have a cancer diagnosis.

145. On various occasions, Insys lied to avoid the federal regulatory schemes and broke guidelines published by the Center for Medicare and Medicaid Services "CMS" by falsely claiming that patients who were enrolled in Aetna's Medicare Part D programs needed Subsys to treat breakthrough cancer pain.

146. In fact, of the millions of dollars in Subsys reimbursements submitted to the Medicare Part D program, less than 1% of prescriptions came from oncologists, the specialty most likely to treat patients with cancer.

147. On one occasion, Insys submitted a prior authorization for a patient enrolled in Aetna's Medicare Part D program claiming that the patient had received a "cancer-pain diagnosis." In September, 2015, after paying for thousands of dollars' worth of Subsys, Aetna discovered that this diagnosis was false and the patient did not have a cancer diagnosis, and immediately revoked the prior authorization.

148. Defendants knew that Subsys was not approved as a pain medication of first resort, and that patients were only supposed to use Subsys if other therapies had been unsuccessful. To gain prior authorization for first-time pain patients, the Insys Defendants developed a "cheat sheet" of drugs to mislead and falsely include in patient medical records so that PAD staff could claim that patients had tried other pain therapies without success.

3. Babich and Gurry Designed a Compensation System that Rewarded Fraud

149. Babich and Gurry structured PAD compensation in a manner that clearly communicated to PAD staff that the only goal was to get Subsys approved by payors like Aetna using any means necessary.

150. The compensation structure provided lucrative biweekly bonuses for PAD staff who obtained excessive prior authorization approvals, regardless of whether the approvals were used to treat breakthrough pain in cancer patients.

151. Gurry established a minimum quota, known as a "gate," that the PAD as a whole had to meet for any of the employees to be eligible for a biweekly performance bonus. Insys knew that there were not enough cancer patients experiencing breakthrough pain to enable PAD staff to meet the "gate," and that the quota would cause PAD staff to deploy fraudulent tactics to obtain the minimum number of prior authorizations.

152. A whistleblower and former PAD employee named Patty Nixon testified before a grand jury that later indicted Babich, Burlakoff, Gurry, Simon, Lee, and Rowan. In June 2017, Nixon had an interview with NBC News where she discussed the fraudulent practices of the PAD.

153. Nixon explained that her supervisor taught the PAD staff how to "trick the insurers into believing it [Subsys] was medically necessary."

154. Nixon further explained that, among other tactics, she would call insurers from Insys PAD facility in Chandler and lie about calling from the doctor's office, saying: "this is Patty. I'm calling from Dr. Smith's office. I'm calling to request prior authorization for a drug called Subsys." Nixon then referred to nonexistent oncology records to trick the insurer and gave specific diagnostic codes corresponding to conditions including cancer that the patient had never been diagnosed with.

155. The PAD was incredibly effective at defrauding insurers like Aetna into paying for off-label, unapproved prescriptions of Subsys. The prior authorization rate for Subsys went from around 30% in 2012 to more than 85% for prescriptions handled by the PAD in 2013.

156. As demonstrated by this dramatic increase in prior authorizations, the PAD's practice of fraudulently obtaining prior authorizations resulted in multi-millions of dollars in reimbursements that Aetna would not have paid but for the fraudulent and deceptive practices employed by Insys PAD.

B. Prong Two: Insys Paid Illegal Kickbacks and Bribes to Physicians to Increase Off-label Subsys Prescriptions

1. The Sham "Speaker Program"

157. In 2012, Insys developed a marketing program to increase the number of prescriptions of Subsys (the "Speaker Program"). The Speaker Program was initially supposed to involve marketing and networking events where a qualified doctor lectured about the use of Subsys in patients with breakthrough cancer pain, but quickly devolved into a program where "speakers" were paid thousands of dollars to attend "dinners" with only the speaker, office staff, and an Insys sales representative.

158. In all, Insys has paid more than $16 million to doctors to prescribe Subsys.

159. Often, the speaker did not even discuss Subsys at all during the events and the events were simply social gatherings at expensive restaurants paid for by Insys.

160. Babich developed the Speaker Program because he was dissatisfied with the sales of Subsys. Babich fired the existing sales staff and brought on replacements who he knew would be amenable to executing the "Speaker Program" for a different reason: bribing doctors to over-prescribe Subsys.

161. For example, in one email to all of Insys' Sales Managers, Babich wrote to ensure that sales staff understood "the important nature of having one of their top targets as speaker. It can pay big dividends for them." By "top targets," Babich meant doctors who he believed would be willing to over-prescribe Subsys, including for off-label uses, because top targets were

typically not cancer doctors but nevertheless wrote a high number of prescriptions for TIRF drugs, and by "big dividends" he meant cash bonuses paid out to sales staff who successfully increased off-label prescriptions in their sales territory.

162. To further determine which doctors qualified as "top targets," Insys ranked doctors into deciles, with practitioners who wrote the most TIRF prescriptions classified in "decile 10."

163. The doctors in "decile 10" were targeted to serve as speakers in the Speaker Program, which carried substantial cash payments and other benefits. A doctor's communication skills, knowledge about pain management, and experience treating cancer patients were not criteria in the selection process. All that mattered was the number of TIRF prescriptions the doctor wrote.

164. Babich repeatedly reminded sales staff that the purpose of the Speaker Program was not to educate doctors about the proper approved use of Subsys or how Subsys could help patients experiencing breakthrough cancer pain. Rather, the goal was to bribe doctors to prescribe the drug for more common, yet unapproved and completely inappropriate, conditions.

165. On one occasion, a sales representative expressed concern to Burlakoff that one of the speakers selected for the program lacked communication skills. Burlakoff reminded the representative that "they do not need to be good speakers, they need to write a lot of [Subsys] prescriptions."

166. Quickly, Insys promoted sales staff who were adept at bribing doctors with speaker fees to increase Subsys prescriptions. These promotions carried increases in pay, as well as overall supervision of Insys' marketing efforts in each region.

167. Burlakoff was promoted to Vice President of Sales for Insys in September 2012. On his first day in that role, he emailed all Regional Sales Managers the following instructions, reminding them that they were required to fire speakers who refused to write more prescriptions for Subsys:

> ...it all starts with choosing the right LOCAL speaker. Your local speaker should be your 'business partner'. You do not work for him, nor does he work for you. You are partners in this endeavor, if your speaker does not see it this way… (then it is time to identify another speaker).

168. Burlakoff, Babich, Simon, Rowan, and Lee repeatedly gave similar instructions via in-person meetings, phone calls, and other secret methods of communication.

169. Insys developed a return on investment metric ("ROI") that tracked and circulated, among other factors (1) the number of Subsys prescriptions written by the speaker, (2) the total amount of "honoraria" (*i.e.* bribes) paid to each speaker, and (3) the "net revenue of profit" Insys earned from each speaker, calculated using factors (1) and (2).

170. This metric did not measure the effectiveness of the speaker's presentations or the accuracy of the speaker's information, since such information would not have led to more unapproved prescriptions for Subsys.

171. Insys used the ROI metric to identify doctors who failed to prescribe the amount of Subsys that Insys expected. Such doctors were targeted by sales staff and were threatened to lose their roles as paid speakers in the Speaker Program.

172. These measures were extremely effective because the bribes were substantial, frequently reaching well above $100,000 for a single "top target" speaker.

2. Insys Targeted Doctors with Few Cancer Patients

173. Babich, Burlakoff, Simon, Lee, and Rowan reviewed data showing that physicians who focused on treating cancer were not "high decile prescribers." Insys targeted

these non-cancer doctors with bribes to take part in the Speaker Program even though Subsys was only approved for use in cancer patients.

174. Babich sent an email to other Insys executives saying "I thought we owned the high decile folks? Lot of big names on there [a list of high-volume prescribers of competitor drugs]." Babich's statement reveals that Insys' goal was to "own" high decile prescribers of TIRFs, even though the "high decile folks" were not cancer doctors.

175. In fact, Insys sales staff were ordered that only doctors who prescribed Subsys off-label to non-cancer patients were eligible for payments under the Speaker Program. On one occasion, Simon texted a sales representative to remind her that speakers were required to promote Subsys for "creative" off-label uses, and were prohibited from mentioning that Subsys was only approved for cancer pain:

> I need confirmation from YOU that you had a conversation with... [the prescriber] where he will not ONLY promote for cancer patients. If he does this he will single handedly take down the whole company. He MUST creatively share how docs write this product everywhere. Please get back to me ASAP with confirmation that he will share with our other speakers how effective ... Subsys will be to treat ALL BTP [Breakthrough Pain].

176. Insys held regular meetings for sales staff where they gave in-person instructions behind closed doors about prescribing Subsys off-label to patients who did not have cancer. For example, at a national sales meeting in 2014, Burlakoff coached sales staff to dismiss actual cancer patients—the only patients who were approved to take Subsys—as "small potatoes" and instead pressure doctors to prescribe Subsys to as many as half of their patients, the majority of whom did not have cancer and thus should never have been prescribed Subsys:

> [t]hese [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the

> [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug.

177. Former Insys sales executive Karen Hill used to work for a competitor that pleaded guilty to marketing TIRF drugs off-label. Hill pleaded guilty to violating the federal Anti-Kickback Statute while at Insys on July 11, 2017. The admissions in her plea agreement further confirm that Insys targeted non-cancer doctors to prescribe Subsys for patients who did not have cancer. Hill told a more junior sales employee:

> Just remember, any doctor, if you have any friends that are doctors, anybody can write this drug. It does not have to be a high decile doctor. Anybody. A script is equal to one script. It does not matter if an oncologist writes it, if a physician's assistant writes it, if a [primary care physician] writes it. It, it does not matter. You just want the scripts coming out, and *the company does not give a s*** where they come from*.

178. The reason that such prescriptions were profitable to Insys is because Insys sales staff knew they could rely on the PAD to defraud insurers into paying for these prescriptions.

179. In addition to "high decile" prescribers, Insys sales staff targeted practitioners that they viewed as particularly vulnerable to bribes because these doctors were most likely to be "willing to speak and get paid to write the prescriptions." Hill coached a junior employee on how to spot such targets:

> I'll tell you how. Any doctor that's money hungry, or that are just going through divorce, or doctors opening up a new clinic, doctors who are procedure heavy. All those guys are money hungry. Doctors that speak for other companies, if they're known as like company whores, you know they speak for everybody, those guys… speaker whores.

180. Natalie Perhacs was an Insys sales representative who pleaded guilty to conspiracy to violate the federal Anti-Kickback Statute for arranging payments to doctors to prescribe Subsys off-label in February 2016. Perhacs had a base salary of $40,000, but she earned $700,000 in commissions as an Insys sales representative because of the high volume of

off-label Subsys prescriptions from doctors in her territory. Perhacs set up speaker programs for two pain management doctors, Dr. Couch and Dr. Ruan, who were convicted of several offenses including conspiracy to receive illegal kickbacks from Insys in exchange for prescribing Subsys.[49]

181. Examples of speakers who were bribed to prescribe Subsys to non-cancer patients abound, and more are emerging.

182. Dr. Jerrold Rosenberg, a Rhode Island doctor specializing in physical medicine and rehabilitation, was reprimanded by the Rhode Island medical board for prescribing Subsys off-label. The doctor received approximately $100,000 from Insys as a speaker, typically receiving up to a $3,700 to give a single "speech."

183. Dr. Paul C. Madison was one of the most prolific prescribers of Subsys in Illinois. The Illinois Attorney General said that Dr. Madison received $84,400 to participate in Insys' "Speaker Program," and only 5% of the patients prescribed Subsys by Dr. Madison were being treated for cancer. Illinois suspended Dr. Madison's license based on "unprofessional conduct and distribution of controlled substances for non-therapeutic purposes." Indiana also suspended Dr. Madison's license. In Michigan, Dr. Madison was fined and restricted from the practice of medicine indefinitely.

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[49] *Dr. Couch and Dr. Ruan Sentenced to 240 and 252 Months In Federal Prison For Running Massive Pill Mill*, U.S. Attorney's Office – S.D. Ala. (May 26, 2017), https://www.justice.gov/usaosdal/pr/drcouchanddrruansentenced240and252monthsfederalprisonrunningmassivepill; *see U.S. v. Couch & Ruan*, No. 1:15-cr-00088 (S.D. Ala.).

3. The "ABL" Program

184. In or around June 2013, Babich, Burlakoff, Simon, and Gurry created the "Area Business Liaison" position ("ABLs") to work in the office of "top target" physicians. These staff members were paid directly by Insys and worked within the physician's office.

185. ABLs were directed to work with Insys PAD to fraudulently obtain prior authorizations for Subsys prescriptions from payors like Aetna.

186. Insys' practices of paying providers was extremely effective and resulted in millions of dollars' in fraudulent Subsys prescriptions for off-label, unapproved uses, much of which was paid for by payors like Aetna.

187. "Top targets" showed a pattern of significantly increasing their off-label prescriptions for Subsys once they were enrolled in the Speaker Program or were given ABLs.

188. One early "top target," Dr. Gavin Awerbuch, was not an oncologist but ran a pain management practice. Dr. Awerbuch averaged about four Subsys prescriptions each week in September 2012. Burlakoff was unsatisfied with Dr. Awerbuch's number of prescriptions.

189. In early October 2012, Burlakoff travelled to take the doctor out to dinner. The following day, Burlakoff emailed Babich and Lee that they could "expect a nice 'bump.'"

190. Between that dinner and the end of November, Dr. Awerbuch prescribed 120 Subsys prescriptions.

191. Over the next year and a half, Burlakoff, Lee, and Babich used the Speaker Program to pay bribes and kickbacks to Dr. Awerbuch. By January 2013, Dr. Awerbuch was averaging about 19 Subsys prescriptions per week, leading Insys to view Dr. Awerbuch as a model "speaker."

192. Dr. Awerbuch was prescribing so much Subsys, mostly to patients that did not have cancer, that Insys hired an ABL to work at Dr. Awerbuch's office to coordinate with PAD staff to fraudulently obtain prior authorizations for Subsys from payors. Insys hired a woman close to Dr. Awerbuch to fill the ABL position, leading Burlakoff to state that the hire was "strategic."

193. In all, payors and pharmacy benefit managers paid for about 2,847 prescriptions for Subsys from Dr. Awerbuch, who was paid approximately $138,435 for participating in the "Speaker Program." Dr. Awerbuch eventually pleaded guilty to distribution of controlled substances and health care fraud, admitting that he that he wrote prescriptions for Subsys to patients "for no legitimate medical purpose."

194. Another "top target," who was also not an oncologist but ran a pain management practice, was prescribing an average of 1.6 Subsys prescriptions each week. Burlakoff was dissatisfied with the ROI and wrote:

> [w]here is ... [the doctor], we cannot go a single day with out [sic] a prescription from ... [the doctor]. I do not want to hear excuses, *we pay good money here* (we need 1 a day from [the doctor] ...)

195. To increase the number of off-label prescriptions from the doctor, Insys hired his girlfriend to serve as "Area Business Liaison" in his office and paid the doctor $275,550 in speaker fees.

196. As a result, Subsys prescriptions from the doctor increased to 7.5 prescriptions each week. Approximately 1,178 Subsys prescriptions from this doctor were paid for by pharmacy benefit managers or payors.

197. Moreover, the success of the Speaker Program and related schemes was not attributable to doctors who treated cancer patients. In 2014, for example, data shows that

oncologists, who should have been the specialists most likely to have patients suffering from breakthrough cancer pain, actually submitted *less than 1%* of all Subsys claims covered through Medicare Part D.

C. The Speaker Defendants Participated in the Conspiracy by Prescribing Subsys Off-Label and in Inappropriate Dosages to Aetna Members

198. The Speaker Defendants were not only aware of the Insys Defendants' scheme: they accepted bribes and/or other perks in exchange for their active participation in it. They agreed to prescribe Subsys off-label and assisted Insys with acquiring their patients' medical records so that the PAD could defraud and induce Aetna into granting prior authorizations.

1. Dr. Steve Fanto

199. Dr. Steve Fanto is a pain medicine doctor in Scottsdale, Arizona who does not specialize in treating cancer patients. However, Dr. Fanto received approximately $234,000 from Insys for participating in its "Speaker Program," including payments up to $6,100 for a single "speaking" event.

200. On July 12, 2017, Dr. Fanto's license to practice medicine was suspended by the Arizona Medical Board. In connection with the suspension, Dr. Fanto executed a consent agreement setting forth certain findings of fact by the medical board.

201. The consent agreement sets forth examples of instances where Dr. Fanto prescribed dangerous opioid painkillers inappropriately. These examples are just a small sampling of Dr. Fanto's improper prescribing practices, but they reveal that Dr. Fanto prescribed Subsys off-label to chronic pain patients who did not have cancer, even though Dr. Fanto knew that Subsys was not approved for off-label use.

202. In one example, Dr. Fanto prescribed a woman experiencing chronic pain an extremely potent and expensive dose of 800 mcg of Subsys, even though it was her first Subsys

prescription. Dr. Fanto knew that first-time Subsys patients are required to use titration and begin with 100 mcg dosage.

203. The Subsys was so strong that the woman could only use 30 units of the 120 units prescribed per month, yet Dr. Fanto continued prescribing the maximum of 120 units per month.

204. Dr. Fanto's prescribing behavior put patients in serious danger, including one patient who tragically died as a result of taking inappropriate opioid pain medication.

205. During the Relevant Period, Dr. Fanto wrote off-label Subsys prescriptions and conspired with Insys to defraud Aetna into paying for approximately $96,000 of Subsys for inappropriate off-label uses and at excessive doses, for which Dr. Fanto knew Aetna did not authorize reimbursement.

206. Dr. Fanto sent patient medical records to Insys PAD, which he knew would equip the PAD to defraud Aetna into paying for excessive dosages of off-label Subsys prescriptions. The higher the dosage, the more the Subsys prescription costs.

207. The speaking fees that Dr. Fanto received from Subsys were rewards for his participation in the fraudulent scheme.

2. Dr. Mahmood Ahmad

208. Dr. Mahmood Ahmad is a pain medicine specialist in Anchorage, Alaska who does not specialize in treating cancer patients. Dr. Ahmad was a "speaker" in Insys' "Speaker Program" who received more than $155,000 in speaking fees from Insys and was one of the most prolific prescribers of Subsys during the Relevant Period.

209. Dr. Ahmad's license was suspended in May 2016 for inappropriately and excessively prescribing opioids, including Subsys. The Alaska State Medical Board suspended

Dr. Ahmad's license, finding that Dr. Ahmad "poses a clear and immediate danger to the public health and safety if he continues to practice medicine."

210. Patient A[50] was an Aetna member patient that was being treated for pain due to cartilage loss in both knees. Patient A did not have a cancer diagnosis, yet received a prescription for Subsys from Dr. Ahmad.

211. Dr. Ahmad's medical office collected an opt-in form from Patient A and sent Patient A's medical records to the PAD so that the PAD could defraud Aetna into paying for Patient A's off-label Subsys prescription.

212. Two Insys PAD employees, who gave their names as "Alyssa" and "David," submitted a prior authorization request for Patient A's Subsys prescription and listed her diagnoses as "Breakthrough Cancer, Dysphagia."

213. Dr. Ahmad wrote off-label Subsys prescriptions and conspired with Insys to defraud Aetna into paying reimbursements for approximately $240,000 of Subsys prescriptions to Aetna members who did not have cancer.

VI. INSYS' SCHEME DEFRAUDED AETNA

214. Insys defrauded Aetna into paying millions of dollars in reimbursements for off-label, unapproved Subsys prescriptions that Aetna would never have authorized had it known the truth. Aetna was victimized by the two-pronged scheme described in this Complaint on repeated occasions during the Relevant Period, as the following examples illustrate.

[50] Patient names have been pseudonymized for patient privacy until such time as the Court issues a protective order providing for the safeguarding of these patients' medical information.

215. Prescriber 1 was a speaker in the Insys Speaker Program who did not specialize in treating cancer patients. Prescriber 1 received approximately $100,000 from Insys in 2014 alone, including as much as $7,500 for a single "speaking" engagement.

216. Patient B was an Aetna member who visited Prescriber 1 for lower back pain, did not have cancer, and received a prescription for Subsys from Prescriber 1.

217. A PAD staff member named "Sheri" contacted Aetna to request prior authorization for Patient B's prescription. On the call, "Sheri" claimed that she was calling from Prescriber 1's office, told the Aetna employee that Patient B had "breast cancer, the ICD10 [diagnostic code] is D50.919," and claimed that the prescription was for "breakthrough cancer pain." These statements were false, and were made by the Insys employee for the purpose of defrauding Aetna into paying for the off-label Subsys.

218. Based on the misrepresentations from "Sheri," Aetna approved the request and paid for Patient B's Subsys.

219. Prescriber 2 was a speaker in the Insys Speaker Program and did not specialize in treating cancer patients. Prescriber 2's practice was located. in Philadelphia, Pennsylvania, for parts of the Relevant Period and is now located in Havertown, Pennsylvania.

220. Prescriber 2 received approximately $117,000 from Insys in "speaking fees." Insys sent these bribes to Prescriber 2 in this Judicial District for sham "speaking events," some of which took place in this Judicial District.

221. Patient C was an Aetna member who saw Prescriber 2 for pain, did not have cancer, and received a prescription for Subsys from Prescriber 2. Upon information and belief, Prescriber 2's staff procured an opt-in form to allow Prescriber 2's staff to forward Patient C's

medical information to Insys PAD so that the PAD could defraud Aetna into paying for Patient C's off-label Subsys prescription. These events all took place in this Judicial District.

222. An Insys PAD staff member called Aetna's PMPU and claimed that Patient C had cancer in order to obtain prior authorization for Patient C's Subsys prescription. At all times, Insys PAD staff knew that they were directing the fraud into this Judicial District because they had Patient C's medical information and knew that the fraudulently procured reimbursement payments from Aetna would be sent into this Judicial District.

223. Aetna paid thousands of dollars for fraudulent, off-label Subsys prescriptions in this Judicial District. Many other episodes like the one involving Patient C took place in this Judicial District during the Relevant Period.

224. Prescriber 3 is a pain medicine specialist who practices in Georgia and Connecticut and does not specialize in treating cancer patients. Prescriber 3 received approximately $58,700 from Insys to participate in its "Speaker Program."

225. Patient D was an Aetna member who saw Prescriber 3 for pain resulting from lumbar radiculopathy, a condition more commonly known as sciatica or a pinched nerve in the lower back. Patient D did not have cancer.

226. Prescriber 3 prescribed Subsys to Patient D, even though Prescriber 3 knew that Subsys was only for breakthrough pain caused by cancer.

227. By the time Aetna learned that Patient D did not have cancer, it had already paid thousands of dollars for Patient D's Subsys.

228. Prescriber 4 is a doctor who practices family medicine in Grand Rapids, Michigan. Prescriber 4 does not specialize in treating cancer patients, yet received approximately $48,100 to participate in Insys' "Speaker Program."

229. Patient E was being treated by Prescriber 4 for lower back pain. Patient E did not have a cancer diagnosis.

230. Insys PAD staff submitted a prior authorization request to Aetna listing the diagnosis as "BREAKTHROUGH CANCER PAIN" and listing the requester's affiliation as "PROVIDER."

231. Based on this information, Aetna granted prior authorization and paid for Patient E's Subsys.

232. It was not until months later that Aetna learned that Patient E had not been diagnosed with cancer.

233. Prescriber 5 is a pain medicine specialist in Miami, Florida. Prescriber 5 does not specialize in treating cancer patients, but did receive approximately $103,100 from Insys to participate in its "Speaker Program."

234. Patient F is an Aetna member who experienced pain from an intervertebral disc in the lower back. Patient F had not been diagnosed with cancer.

235. In July 2015, Aetna's PMPU received a call from a person named "Ricki" using a phone number that matched the number for Prescriber 5's office, although "Ricki" was actually calling from Insys PAD facility in Arizona. "Ricki" falsely claimed that Patient F was prescribed Subsys by Prescriber 5 for "breakthrough cancer pain."

236. Based on this false information, Aetna granted prior authorization for the Subsys prescription and paid for Patient F's Subsys.

237. In October 2015, an Aetna employee called Prescriber 5's office and learned that Patient F had no history of cancer.

238. Prescriber 6 was a speaker in the Insys "Speaker Program" and a physical medicine and rehabilitation doctor in Colorado. Prescriber 6 received $294,000 from Insys to participate in its Speaker Program.

239. Patient G was an Aetna member who was being treated by Prescriber 6 for lumbar scoliosis, lumbar spinal stenosis, lumbar post-laminectomy syndrome, and thoracic pain. Patient G did not have cancer.

240. Prescriber 6 convinced Patient G to switch to Subsys for her pain issues, despite the fact that Patient G did not have cancer. The doctor assured Patient G that, though she had to be approved by Aetna to receive the medication, he would "make sure" she got approval.

241. The patient was intimidated by the packaging, and Subsys made the patient sick, but Prescriber 6 told her that Subsys could not be returned. As a result, Aetna paid more than $20,000 for the patient's Subsys prescription, for which Insys fraudulently obtained prior authorization.

242. Prescriber 7 is a doctor practicing emergency medicine in New York, New York. Prescriber 7 does not focus on treating cancer patients yet received more than $200,000 to participate in Insys' Speaker Program.

243. Patient H was an Aetna member who saw Prescriber 7 for pain. Patient H was not diagnosed with cancer.

244. An Insys PAD staff member who gave the name "Ricki" called Aetna's PMPU and falsely claimed that Patient H needed Subsys for "breakthrough cancer pain – Anal Cancer." Based on "Ricki's" fraudulent statements, Aetna approved the prescription.

245. Several months later, an Aetna employee followed up on Patient H's treatment by calling Prescriber 7's office. One of Prescriber 7's employees answered and revealed that Prescriber 7 had never treated Patient H for cancer pain.

246. Aetna immediately overturned the approval and refused to reimburse the next prescription, but not before it had already paid thousands of dollars for Patient H's Subsys.

247. Prescriber 7 initiated an appeal with medical records that revealed that Patient H did not have a cancer diagnosis.

248. An Aetna employee handling the appeal called Prescriber 7's office. The employee from Prescriber 7's office reported, falsely, that Patient H was being treated for breakthrough cancer pain.

249. In all, Aetna paid tens of millions of dollars for fraudulently procured Subsys prescriptions for non-cancer patients during the Relevant Period.

VII. FRAUDULENT CONCEALMENT

250. Throughout the Relevant Period, Defendants through fraud or concealment caused Aetna to relax its vigilance or deviate from its right of inquiry into the facts.

251. Plaintiffs were defrauded by Defendants having their employees disguise the true identity and location of their employer, and lie and mislead about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication.

252. Because of Defendants' fraudulent concealment, the existence of Plaintiffs' injury was not known and knowledge could not reasonably be ascertained within the prescribed statutory period. Aetna did not have sufficient critical facts to put it on notice that wrongs had been committed and that it needed to investigate to determine whether it was entitled to redress.

Aetna was unable to know it had been injured by the fraudulent acts of Defendants despite the exercise of reasonable diligence.

253. The existence of the scheme described in this Complaint was kept secret and could not reasonably have been uncovered earlier than July 2015, when Southern Investigative Reporting Foundation released its report entitled "The Black World of Insys Therapeutics."[51] Aetna was diligent in pursuing an investigation of the claims asserted in this Complaint, but did not receive inquiry notice, nor did it learn of the factual basis for the claims in this Complaint and the injuries it suffered, until or after July 2015.

254. The fraudulent scheme described in this Complaint was inherently self-concealing and needed to be kept hidden to succeed. Insys made great efforts to conceal the scheme and used the following affirmative means:

a. Insys PAD staff lied to and misled Aetna about patients' medical histories, including fake cancer diagnoses;

b. Insys installed systems on PAD telephone lines to list on caller ID false area codes corresponding with patients' doctors' offices and directed PAD staff to impersonate employees at patients' doctor's offices;

c. Insys PAD staff sent Aetna falsified medical records and falsely claimed or misled Aetna that patients were suffering from breakthrough cancer pain, had dysphagia and/or neoplasms, and had tried and failed less expensive medications;

d. Insys bribed doctors using secret cash payments to prescribe Subsys for off-label use and misrepresented to the public that the doctors were only being paid for their "speaking" at educational events;

e. Insys took affirmative steps to create the false and misleading impression that the "Speaker Program" existed to reimburse qualified speakers for speaking at bona fide educational events;

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[51] Roddy Boyd, *The Black World of Insys Therapeutics*, SOUTHERN INVESTIGATIVE REPORTING FOUNDATION (Jul. 14, 2015), available at http://sirf-online.org/2015/07/14/the-darkening-world-of-insys-therapeutics/ (last visited Aug. 17, 2017).

f. Insys' fraudulent scheme constitutes continuous and ongoing violations of law that continue through the present day.

255. Plaintiffs thus assert the tolling of the applicable statutes of limitations affecting the rights of the claims for relief asserted. Defendants are also equitably estopped from asserting that any otherwise applicable limitations period has run.

VIII. CAUSES OF ACTION

COUNT I
INSURANCE FRAUD
Violation of 18 Pa. C.S.A. § 4117(a)(2)

256. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

257. The Pennsylvania Insurance Fraud Statute, 18 Pa. C.S.A. § 4117(a)(2), provides that a person commits an offense if the person:

> knowingly and with the intent to defraud any insurer or self-insured, presents or causes to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim.

258. The Defendants knowingly and with intent to defraud engaged in a pattern of causing false, incomplete, and misleading insurance claim information to be presented to Aetna.

259. The Defendants submitted false statements knowingly to Aetna. The statements were false in fact, and Defendants knew that they were false when they were made by or on behalf of Defendants.

260. The Insys Defendants' fraudulent schemes consisted of: (a) causing providers to misrepresent the off-label use(s) for which Subsys was being prescribed so that Aetna and its members were unaware that they were paying Subsys claims for off-label uses; (b) deliberately lying about and misrepresenting patient medical records so that Aetna unwittingly paid for

Subsys to treat symptoms for which it was not scientifically proven to be safe and effective and for which it had not been approved of by the FDA.

261. The Speaker Defendants misrepresented the improper use(s) for which Subsys was being prescribed so that Aetna and its members were unaware that they were paying Subsys claims for improper uses; completed out opt-in forms for patients and faxed or emailed forms to the PAD from offices located throughout the United States, including Pennsylvania, in order for the PAD to deliberately lie about and misrepresent patient medical records. These actions caused Aetna to unwittingly pay for Subsys to treat symptoms for which it was not scientifically proven to be safe and effective, for which it had not been approved of by the FDA, and for which Insys knew Aetna did not authorize reimbursement.

262. Defendants' schemes discussed in the previous paragraphs were calculated to ensure that Plaintiffs would be wrongfully induced to cover, and then be over-billed for Subsys.

263. Each of the fraudulent acts detailed above constitutes "Insurance Fraud" within the meaning of 18 Pa. C.S.A. § 4117(a). Collectively, these violations constitute a pattern of insurance fraud within the meaning of 18 Pa. C.S.A. § 4117(g).

264. Much of the wrongful, deceptive, and unfair conduct detailed in this Complaint took place in Pennsylvania and/or caused injury to Aetna and others in Pennsylvania.

265. The Defendants were aware that Aetna depended on the accuracy of patients' medical diagnoses when deciding whether to approve and pay for Subsys prescriptions.

266. The above-described pattern of insurance fraud amounted to a common course of conduct intended to deceive Aetna. Each fraudulent act was related, had similar purposes, involved similar participants and methods of commission, and had similar results affecting similar victims, including Aetna. The Defendants' fraudulent activities were and are part of its

regular way of conducting its ongoing business, and constitute a present and continuing threat to the property of Aetna.

267. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and acts committed in furtherance thereof, Aetna has suffered injury and has been damaged as alleged herein.

268. By virtue of these violations of 18 Pa. C.S.A. § 4117, Defendants are liable to Aetna for three times the damages sustained, plus investigation expenses, costs of this suit, and reasonable attorneys' fees and expenses.

COUNT II
INSURANCE FRAUD
Violation of 18 Pa. C.S.A. § 4117(a)(3)

269. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

270. The Pennsylvania Insurance Fraud Statute, 18 Pa. C.S.A. § 4117(a)(3), provides that a person commits an offense if the person:

> Knowingly and with the intent to defraud any insurer or self-insured, assists, abets, solicits or conspires with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim . . .

271. The Defendants knowingly and with intent to defraud engaged in a pattern of assisting, abetting, soliciting or conspiring with providers to cause false, incomplete, and misleading insurance claim information to be presented to Aetna.

272. The Defendants submitted false statements knowingly to Aetna. The statements were false in fact, and Defendants knew that they were false when they were made by or on behalf of Defendants.

273. The Insys Defendants set up the "Prior Authorization Department" ("PAD") to have Insys employees pose as providers' office staff and provide false, incomplete or misleading information concerning medical facts material to the claims in order to gain prior authorization for Subsys from Aetna.

274. The Insys Defendants unlawfully conspired with providers, including Speaker Defendants, to have the providers use the PAD rather than their own office staff to navigate the prior authorization process. The PAD assisted providers, including Speaker Defendants, by providing false, incomplete or misleading information to Plaintiffs regarding material facts from patient medical records so that Plaintiffs would provide prior authorization for Subsys. Providers that agreed to use the PAD, including Speaker Defendants, completed out opt-in forms for patients and faxed or emailed forms to the PAD from the offices of practitioners located throughout the United States, including Pennsylvania.

275. Aetna unwittingly paid for Subsys to treat symptoms for which it was not scientifically proven to be safe and effective and for which it had not been approved of by the FDA.

276. The Insys Defendants unlawfully conspired with providers, including the Speaker Defendants, to prescribe Subsys through the Speaker Program described above. The Insys Defendants provided payments and other forms of kickbacks to providers who would agree to prescribe Subsys, including Speaker Defendants, to treat symptoms for which it was not scientifically proven to be safe and effective and for which it had not been approved of by the FDA and misrepresent the off-label use(s) for which Subsys was being prescribed so that Aetna and its members were unaware that they were paying Subsys claims for off-label uses.

277. Defendants' schemes discussed in the previous paragraphs were calculated to ensure that Aetna would be wrongfully induced to cover, and then be over-billed for Subsys.

278. Each of the fraudulent acts detailed above constitutes "Insurance Fraud" within the meaning of 18 Pa. C.S.A. § 4117(a). Collectively, these violations constitute a pattern of insurance fraud within the meaning of 18 Pa. C.S.A. § 4117(g).

279. Much of the wrongful, deceptive, and unfair conduct detailed in this Complaint took place in Pennsylvania and/or caused injury to Aetna and others in Pennsylvania.

280. The Defendants were aware that Aetna depended on the accuracy of patients' medical diagnoses when deciding whether to approve and pay for Subsys prescriptions.

281. The above-described pattern of insurance fraud amounted to a common course of conduct intended to deceive Aetna. Each fraudulent act was related, had similar purposes, involved similar participants and methods of commission, and had similar results affecting similar victims, including Aetna. The Defendants' fraudulent activities were and are part of its regular way of conducting its ongoing business, and constitute a present and continuing threat to the property of Aetna.

282. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and acts committed in furtherance thereof, Aetna has suffered injury and has been damaged as alleged herein.

283. By virtue of these violations of 18 Pa. C.S.A. § 4117, Defendants are liable to Aetna for three times the damages sustained, plus investigation expenses, costs of this suit, and reasonable attorneys' fees and expenses.

COUNT III
CIVIL CONSPIRACY

284. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

285. The Defendants combined with a common purpose to commit insurance fraud, commit common law fraud, and enrich themselves at Plaintiffs' expense. By engaging in the conduct alleged in this Complaint, Defendants have intentionally and wrongfully engaged in a combination and conspiracy.

286. The object of the conspiracy was to cause payors including Aetna to pay for off-label, unapproved Subsys prescriptions for which Aetna would have never approved coverage reimbursement had it known the truth.

287. Insys agreed to and did pay the Speaker Defendants money that was supposed to be for speaking at education events, but was actually in return for the Speaker Defendants' reciprocal agreement to prescribe Subsys off-label to non-cancer patients and to forward the patient's medical information to Insys PAD.

288. The Speaker Defendants agreed to and did prescribe Subsys off-label to patients who did not have cancer and forwarded patient medical records to the PAD, knowing that the PAD would use them to fraudulently procure reimbursement from Aetna.

289. The Speaker Defendants accepted cash kickbacks in exchange for their participation in the scheme described in this Complaint.

290. Aetna suffered actual legal damage as a direct and proximate result of Defendants' conspiracy to defraud Aetna into reimbursing payments for off-label, unapproved Subsys prescriptions. Aetna's injuries consist of the reimbursements for off-label, unapproved Subsys prescriptions. These injuries flow from the Defendants' unlawful conduct as alleged in this Complaint.

291. Plaintiffs seek damages as permitted by law for its injuries caused by Defendants.

COUNT IV
COMMON LAW FRAUD

292. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

293. The Defendants' misrepresentations discussed herein were material to the amounts Aetna reimbursed for prescriptions of Subsys.

294. The misrepresentations were made with knowledge of their falsity or with reckless disregard for its truth.

295. The misrepresentations were made with the intent to induce Aetna into relying on its truth in order to make payments.

296. The misrepresentations were calculated to deceive, whether by single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or by innuendo, by speech or silence.

297. Aetna justifiably relied upon the misrepresentations made by or on behalf of the Defendants.

298. By reason of the foregoing, and as a proximate cause of said fraud and acts committed in furtherance thereof, Aetna has suffered injury and has been damaged as alleged herein.

299. The acts alleged were malicious, oppressive and contrived for the purpose of achieving the objects of the fraud. Therefore, Aetna is entitled to punitive damages.

COUNT V
UNJUST ENRICHMENT

300. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

301. Aetna has conferred on Defendants substantial financial benefits in the form of payments for Subsys that would not have been made had Defendants not engaged in the wrongful acts and practices alleged herein.

302. Retention of the payments and other benefits by Defendants would be inequitable and unjust under the circumstances of this case because Defendants' deceptive conduct caused Plaintiffs to pay for Subsys when Plaintiffs would otherwise not have.

303. Defendants have been unjustly enriched by wrongfully securing benefits from Aetna, and it would be unconscionable for Defendants to retain them.

304. In fairness, under the equitable doctrine of unjust enrichment, Defendants should be required to disgorge to Aetna the revenues or profits Defendants earned from their improper sales of Subsys to Aetna's members.

COUNT VI
NEGLIGENT MISREPRESENTATION

305. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

306. Defendants misrepresented material facts to Aetna. The Defendants either knowingly and with intent to mislead Aetna or without conducting a reasonable investigation of the truth of their misrepresentations, engaged in a pattern of assisting, abetting, soliciting or conspiring with providers to cause false, incomplete, and misleading insurance claim information to be presented to Aetna.

307. The Defendants submitted statements that were false, or that Defendants should have known were false, to Aetna. Defendants knew or should have known that they were false when they were made by or on behalf of Defendants.

308. The above-described pattern of misconduct was intended to, and did, induce Aetna to authorize coverage or pay for Subsys prescriptions that were otherwise improper. The

Defendants' misconduct was part of its regular way of conducting its ongoing business, and, if continued, constitutes a present and continuing threat to the property of Aetna.

309. Defendants had a pecuniary interest in securing improper authorization for the prescription of Subsys and supplied Aetna false information in their business transactions and failed to exercise reasonable care or competence in obtaining or communicating the information to Aetna.

310. Defendants knew that Aetna would rely upon their representations and knew or could reasonably foresee that Aetna would take action, in the form of authorizing coverage, based upon Defendants' misrepresentations. These misrepresentations induced Aetna to authorize coverage for a dangerous opioid, at unnecessary and increased expense to Aetna and its members. Under the circumstances here, and as set forth more fully above, Defendants owed Aetna a duty of candor to not intentionally or negligently misrepresent the medical conditions of Aetna's members.

311. The known, lethal and dangerous qualities and risks associated with a powerful opioid such as Subsys violated Insys' heightened duty of care to ensure that Subsys was not improperly prescribed.

312. Defendants had a duty to ensure that its employees or those acting on its behalf acted truthfully and honestly in the sales, marketing and inducements utilized to authorize or pre-certify prescriptions for Subsys that they knew or should have known would not otherwise qualify for authorization or reimbursement by Aetna.

313. Aetna justifiably and reasonably relied upon the Defendants' misstatements.

314. Aetna was damaged and suffered pecuniary loss as a result of Defendants' misstatements.

COUNT VII
NEGLIGENCE

315. Plaintiffs incorporate the preceding paragraphs as if fully set forth below.

316. In conducting this improper activity through servants or other agents, Defendant Insys is subject to liability for harm resulting from its conduct.

317. Defendants knew or should have known that the misconduct described more fully above would or was likely to cause Aetna damages.

318. Defendants had a duty to ensure that its employees or those acting on its behalf acted truthfully and honestly in the sales, marketing and inducements utilized to authorize or pre-certify prescriptions for Subsys that they knew or should have known would not otherwise qualify for authorization or reimbursement by Aetna.

319. The Insys Defendants knew the lethal and dangerous qualities and risks associated with the powerful opioid Subsys and violated their heightened duty of care to ensure that Subsys was not improperly prescribed.

320. Defendant Insys improperly directed or failed to supervise its employees who implemented and engaged in the misconduct designed to improperly increase Subsys sales.

321. Defendants failed to train, supervise and create or enforce proper standards for employees to not engage in these types of misconduct as set forth more fully above.

322. The Insys Defendants knew about Insys' problematic prior authorization practices and that it "lacked formal policies or monitoring procedures to ensure proper communication between Insys employees and healthcare professionals" but failed to implement "sufficient

compliance processes to prevent fraud and was internally aware of the danger of problematic practices."[52]

323. Defendants employed improper persons who were not qualified or trained to act on its behalf in a lawful manner and who engaged in the misconduct described above.

324. Defendants were reckless, willful and/or careless in supervising or failing to supervise employees who were engaged in the misconduct described above.

325. Defendants were reckless, willful and/or careless in supervising or failing to supervise employees who were engaged in the misconduct described above.

326. The Defendants' misconduct discussed herein caused Aetna to reimburse for improper prescriptions of Subsys.

327. The Defendants' misconduct discussed herein caused Aetna to reimburse for improper prescriptions of Subsys.

328. By reason of the foregoing, and as a proximate cause of said negligence committed in furtherance thereof, Aetna has suffered injury and has been damaged as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(a) On Plaintiffs' First and Second Counts under Pennsylvania's Insurance Fraud Statute, three times the damages Plaintiffs have sustained as a result of the Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' investigative expenses and costs of suit, reasonable attorneys' fees and expenses, and prejudgment and post-judgment interest;

[52] Exhibit A at 4.

(b) On Plaintiffs' Third, Fourth, Sixth, and Seventh Counts, actual and punitive damages, such amounts to be determined at trial, plus costs of suit, reasonable attorneys' fees and expenses, and prejudgment and post-judgment interest;

(c) On Plaintiffs' Fifth Count, an award to Plaintiffs of disgorgement of all sums improperly received by Defendants;

(d) An award of prejudgment interest in the maximum amount allowable by law;

(e) An award to Plaintiffs of their costs and expenses in this litigation and reasonable attorneys' and expert fees and expenses; and

(f) An award to Plaintiffs of such other and further relief as may be just and proper under the circumstances.

REQUEST FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

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Dated: September 18, 2017

Attorneys for Plaintiffs

VERIFICATION

I, Gerald Lawrence, hereby state that I am an attorney for the Plaintiffs and that I am authorized to make this Verification on behalf of the Plaintiffs; that the parties which I represent lack sufficient knowledge or information upon which to make this Verification and/or that this Verification is made on behalf of parties from whom a verification could not be obtained; and that the facts set forth in the foregoing Complaint are true and correct to the best of my knowledge, information, and belief.

I understand that the statements herein are made subject to the penalties of 18 Pa. C.S.A. § 4904 (relating to unsworn falsification to authorities).

Dated: September 18, 2017

/s/ Gerald Lawrence
Gerald Lawrence, Esquire

EXHIBIT A

HSGAC
MINORITY STAFF REPORT

Fueling an Epidemic

Insys Therapeutics and the Systemic Manipulation of Prior Authorization

U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office

HSGAC
MINORITY

Fueling an Epidemic

Insys Therapeutics and the Systemic Manipulation of Prior Authorization

The opioid epidemic has exacted a staggering human and financial cost in the United States over the past 20 years. Approximately 183,000 Americans died from prescription opioid overdoses between 1999 and 2015, with more than 15,000 Americans dying in 2015 alone.[1] According to the Centers for Disease Control and Prevention (CDC), in 2015 "[t]he age-adjusted rate of drug overdose deaths in the United States in 2015...was more than 2.5 times the rate in 1999."[2] Provisional 2016 statistics from the CDC also show that "[d]rug deaths involving fentanyl more than doubled from 2015 to 2016," and "deaths involving synthetic opioids, mostly fentanyls, have risen to more than 20,000 from 3,000 in just three years."[3] In Missouri, the rate of prescription opioid-related inpatient hospitalizations and emergency room visits more than doubled from 187 per 100,000 to 424 per 100,000 between 2005 and 2014.[4] Similarly, Medicare Part D spending on commonly abused opioids increased 165% between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.[5]

In response to this crisis, Sen. McCaskill issued wide-ranging requests for documents related to opioid sales and marketing efforts to five major opioid manufacturers.[6] These requests focused on internal estimates concerning the risk of opioid addiction, compliance audits and reports concerning sales and marketing policies, marketing and business plans, materials related to manufacturer payments to physicians and manufacturer-created physician presentations, funding of educational materials targeted to opioid-prescribing physicians, and funding for major pain advocacy groups and other groups. In response, the minority staff has received thousands of pages of internal company documents, including extensive materials from Insys Therapeutics.

Drawing on these documents and other materials, this report provides new information regarding the significant efforts Insys has undertaken to reduce barriers to the prescription of Subsys, its powerful fentanyl product. These efforts include actions to mislead pharmacy benefit managers (PBMs) about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients. An internal Insys document suggests Insys apparently lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies. In the case of Subsys patient Sarah Fuller, an audio recording reveals that an Insys employee repeatedly misled representatives of Envision Pharmaceutical Services

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[1] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Aug. 1, 2017) (www.cdc.gov/drugoverdose/data/overdose.html).
[2] Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999–2015* (Feb. 24, 2017) (www.cdc.gov/nchs/products/databriefs/db273.htm).
[3] *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, New York Times (Sept. 2, 2017) (www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html).
[4] Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (www.mhanet.com/mhaimages/HIDIHealthStats/ Opioids_HealthStats_1015.pdf).
[5] Department of Health and Human Services Office of Inspector General, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (OEI-02-16-00290) (June 21, 2016); Department of Health and Human Services Office of Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing* (OEI-02-17-00250) (July 13, 2017).
[6] Letter from Sen. Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Insys Therapeutics, Inc. (March 28, 2017).

to obtain approval for her prescription. The result, in the case of Ms. Fuller, was death due to allegedly improper and excessive Subsys use.

BACKGROUND ON INSYS THERAPEUTICS AND SUBSYS

Insys Therapeutics was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[7] In 2012, Insys received U.S. Food and Drug Administration (FDA) approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain, and the drug proved incredibly successful financially.[8] Insys had "the best-performing initial public offering in 2013," and, over the next two years, revenues tripled and profits rose 45%.[9] The value of company stock increased 296% between 2013 and 2016.[10]

To prevent the overprescription and abuse of powerful and expensive drugs like Subsys, insurers—often using PBMs—employ a process known as prior authorization. As noted in a Permanent Subcommittee on Investigations report Sen. McCaskill and Sen. Rob Portman issued on October 4, 2016, the prior authorization process "requires additional approval from an insurer or its pharmacy benefit manager before dispensing. ... Prior authorization policies can also impose 'step therapy,' which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach."[11]

With regard to Insys specifically, recent court filings explain that insurers have "required that a prior authorization be obtained before a claim [can] be submitted for a Subsys® prescription."[12] This process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys® to treat breakthrough pain that the other opioid could not eliminate. If any one of those factors was not present, the prior authorization would be denied ... meaning no reimbursement would be due."[13]

These screening processes reportedly raised significant obstacles to Subsys prescriptions shortly after Insys introduced the drug. According to a criminal indictment filed against former Insys CEO Michael Babich and five other Insys executives, an internal company analysis in November 2012 revealed that insurers and PBMs approved reimbursements for Subsys in only approximately 30% of cases.[14]

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[7] *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016) (www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968).
[8] *Id.*
[9] *Id.*
[10] *An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain*, Forbes (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).
[11] Senate Permanent Subcommittee on Investigations, *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems* (Oct. 4, 2016); *see also* Department of Health and Human Services, Centers for Medicare & Medicaid Services, *How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules* (Oct. 2015).
[12] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).
[13] *Id.*
[14] Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

In response to these challenges, Insys allegedly created a prior authorization unit, known at one point as the Insys Reimbursement Center (IRC), to intervene with PBMs and secure reimbursements between January 2013 and October 2016.[15] Led by an Insys employee named Elizabeth Gurrieri, IRC employees reportedly received significant financial incentives and management pressure—including quotas and group and individual bonuses—to boost the rate of Subsys authorizations.[16] According to Patty Nixon, a former Insys employee, Ms. Gurrieri personally pressured IRC employees to improve the rate of prescription approvals, noting that "Dr. Kapoor's not happy, we have to get these approvals up."[17]

IRC employees allegedly met this demand through a number of techniques. Employees, for example, reportedly falsified medical histories for prospective Subsys patients, "fraudulently assert[ing] that a patient had a cancer diagnosis regardless of the patient's history and regardless of whether the prescriber had prescribed Subsys® for a different diagnosis."[18] In response to increased scrutiny from PBMs and the U.S. Department of Health and Human Services, Insys allegedly developed a canned response to questions concerning whether a potential Subsys patient suffered from breakthrough cancer pain. In this response, Insys employees stated that "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients [and] [t]he physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."[19] According to an affidavit filed in support of criminal charges against Ms. Gurrieri, the script "deliberately omitted the word 'cancer' in order to mislead agents of insurers and PBMs."[20]

The IRC also allegedly misled PBMs and insurers about the unit's role in facilitating approvals for Subsys.[21] To prevent PBMs from tracing calls back to Insys, for example, the IRC obscured its outgoing phone number on caller ID.[22] When PBMs required a phone number for a return call, Insys employees reportedly provided a 1-800 number manned by another Insys representative—instead of contact information for the prescribing physician.[23] Insys executives also allegedly told IRC employees to claim they were calling "from" a physician's office; later, "employees were instructed to tell agents of insurers and pharmacy benefit managers that they were calling 'on behalf' of a specific doctor, and were 'with' a specific doctor's office."[24]

According to a class action lawsuit, Insys management "was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice investigation found that 78% of preauthorization forms submitted

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[15] *See* Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).
[16] *Murder Incorporated: Insys Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015) (sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/); *see also* Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).
[17] *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016).
[18] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).
[19] Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).
[20] Affidavit of Special Agent Paul S. Baumrind, Federal Bureau of Investigation, In Support of a Criminal Complaint and Arrest Warrant (Oct. 12, 2016), *United States v. Gurrieri*, D. Mass. (No. 1:17 CR 10083); *see also* Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).
[21] Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).
[22] *Murder Incorporated: Insys Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015); *see also* Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).
[23] *Murder Incorporated: Insys Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015).
[24] Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

by Insys on behalf of Oregon patients were for off-label uses.[25] In just one example, an Anthem review of Subsys claims "revealed that 54% of members with Subsys® prescriptions that had been reimbursed by Anthem did not actually have an underlying cancer diagnoses," and "[f]or an additional 6% of members with reimbursed Subsys® prescriptions, it was unclear whether Subsys® was properly prescribed."[26] Anthem estimates that it "paid over $19 million in reimbursements for Subsys® prescriptions that were not covered by Anthem's plans."[27]

INSYS KNEW ABOUT PROBLEMATIC PRIOR AUTHORIZATION PRACTICES AND FAILED TO TAKE CORRECTIVE ACTION

Internal Insys documents suggest the company knew—more than a year before the events involving Sarah Fuller, described below—that the IRC lacked formal policies or monitoring procedures to ensure proper communication between Insys employees and healthcare professionals. Insys, in other words, lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies.

In an internal presentation dated 2012 and entitled, "2013 SUBSYS Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[28] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1-800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."[29]

Additional materials produced by Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note, Email, & IRC Verbatim Data Audit Report."[30] The introduction to the report explained that "CIS was approached by INSYS' legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented."[31] Insys had expressed concerns "with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements."[32] An additional concern

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[25] *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 4, 2015) (www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html).
[26] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*, D. Ariz. (No. 2:17 CV 02286).
[27] *Id.*
[28] Insys Therapeutics, Inc., *2013 Subsys Brand Plan, 2012 Assessment* (2012) (INSYS_HSGAC_00007472) (selected slides attached as Exhibit A).
[29] *Id.* at INSYS_HSGAC_00007473.
[30] Compliance Implementation Services, *Insys Call Note, Email & IRC Verbatim Data Audit Report* (Feb. 18, 2014) (INSYS_HSGAC_00007763) (attached as Exhibit B).
[31] *Id.* at INSYS_HSGAC_00007765.
[32] *Id.*

"stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[33]

Given these issues, Insys requested that CIS review—in part—"the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers ... to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product."[34]

According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists...that governs the support function of obtaining a prior authorization for the use of SUBSYS."[35] In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC."[36] In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."[37] Although four informal standard operating procedures existed with regarded to IRC functions, these documents "lacked a formal review and approval" and failed to "outline appropriately the actions performed within the IRC."[38]

The report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner."[39] More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."[40]

At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management "formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs."[41] Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures "specific to each job function within the IRC," accompanied by "adequate training and understanding of these processes."[42] To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow

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[33] *Id.*
[34] *Id.*
[35] *Id.* at INSYS_HSGAC_00007770.
[36] *Id.* at INSYS_HSGAC_00007768.
[37] *Id.* at INSYS_HSGAC_00007771.
[38] *Id.* at INSYS_HSGAC_00007770.
[39] *Id.* at INSYS_HSGAC_00007769.
[40] *Id.* at INSYS_HSGAC_00007771.
[41] *Id.* at INSYS_HSGAC_00007770.
[42] *Id.* at INSYS_HSGAC_00007771.

management "to monitor both live and anonymously IRC employee communications both incoming and outgoing."[43] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[44]

The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed "that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated."[45] Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

INSYS REPRESENTATIVE SOUGHT AUTHORIZATION FOR PATIENT SARAH FULLER

As part of its investigation, the minority staff received an audio recording of conversations between an Insys employee and PBM representatives related to a Subsys prescription for Sarah Fuller, who later died from an alleged fentanyl overdose. This recording suggests the IRC employee in question repeatedly misled Envision Pharmaceutical Services to obtain approval for Subsys treatment for Ms. Fuller.

The recording reveals that the Insys employee identified herself as being "with" the office of Ms. Fuller's doctor; in the second conversation, the employee confirms she is "calling from the doctor's office." The Insys employee also states that Subsys is "intended for the management of breakthrough cancer pain" without explicitly claiming that Ms. Fuller suffers from this type of pain. She then states that Ms. Fuller suffers from breakthrough pain—pointedly dropping "cancer" from the description. Later, when asked whether the Subsys prescription will treat "breakthrough cancer pain or not," the Insys employee sidesteps the question by merely stating there is "no code for breakthrough cancer pain." She then reaffirms that the prescription is "for breakthrough pain, yeah."

Background about Sarah Fuller

According to a March 23, 2017, complaint filed in the Superior Court of Middlesex County, New Jersey, Sarah A. Fuller died from a Subsys overdose on March 25, 2016.[46] In 2014, Ms. Fuller allegedly sought treatment under the care of Dr. Vivienne Matalon of Cherry Hill to manage the medications she took for various health conditions, including fibromyalgia and back pain.[47] During this initial consultation, Ms. Fuller's parents indicated she had previously overcome an addiction to narcotic pain medication; despite this information, Dr. Matalon

[43] *Id.*
[44] *Id.*
[45] *Id.* at INSYS_HSGAC_00007772.
[46] Complaint (March 23, 2017), *Fuller v. Matalon, et al.*, Middlesex Cty. Sup. Ct. (No. L1859-17).
[47] *Id.*

prescribed OxyContin and Percocet to Ms. Fuller over the next few months.[48] In January 2015, Dr. Matalon, Ms. Fuller, and her father allegedly met with an Insys representative to discuss Subsys as a remedy for Ms. Fuller's neck and back pain.[49] According to the complaint, "[n]either the Insys sales representative nor Dr. Matalon informed Sarah or her father that Subsys was fentanyl and that it was only approved and indicated for patients that were experiencing breakthrough cancer pain from malignant cancer."[50]

Over the next several months, Ms. Fuller received increasing amounts of Subsys on a monthly basis until she was admitted, on October 28, 2015, to a local hospital suffering from "hyper-sedation with hypoxia secondary to narcotics and sedatives."[51] Despite instructions to discontinue Subsys—included in medical records provided to Dr. Matalon—Ms. Fuller received additional Subsys prescriptions, along with prescriptions for Percocet, OxyContin, and Alprazolam, over the next five months.[52] On March 25, 2016, Ms. Fuller died "due to an adverse reaction to prescription medications."[53] During the 14-month period in which Ms. Fuller received Subsys treatment, Medicare paid as much as $24,000 per month for the prescriptions.[54]

According to the Centers for Medicare & Medicaid Services (CMS) Open Payments database, Dr. Matalon received almost $600 in payments from Insys in 2015.[55] Although this amount pales in comparison to other payments physicians have received from the company, a clear link exists between even minimal manufacturer payments and physician prescribing practices. A 2016 study published in *JAMA Internal Medicine*, for example, found "a significant association between [a physician] attending a single meal promoting a specific drug, with a mean value of less than $20, and the prescribing of the promoted drug over therapeutic alternatives."[56] In addition, "additional meals and costlier meals [were] associated with greater increases in prescribing of the promoted drug."[57] *ProPublica* has similarly found that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."[58]

Insys Representative Misleads PBM to Obtain Prior Authorization

The minority staff has obtained an audio recording of a conversation between an Insys employee and the PBM Envision, which provided prior authorization services in connection

[48] *Id.*
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Open Payments Data, Centers for Medicare & Medicaid Services, Physician Profile for Vivienne I. Matalon (openpaymentsdata.cms.gov/physician/153888/payment-information) (accessed July 18, 2017).
[56] Colette DeJong, et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, JAMA Internal Medicine (June 20, 2016).
[57] *Id.*
[58] *Now There's Proof: Docs Who Get Company Cash Tend to Prescribe More Brand-Name Meds*, ProPublica (March 17, 2016) (www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs).

with the Subsys prescription for Ms. Fuller. During this January 2015 conversation, an IRC employee discussed prior authorization for Subsys with a representative from Convey Health Solutions, a call center support vendor for Envision Pharmaceutical Services, as well as a member of the clinical department of EnvisionRx Plus.

In the first portion of this recording, the Insys employee begins her conversation with a PBM representative by misleadingly identifying herself as "with the doctor's office." At no point does the employee identify herself as working for Insys or explain she is calling from an Insys office. After being transferred to the Envision clinical department for further questioning, the Insys employee confirms she is calling "from" a doctor's office and claims the prior authorization request is "urgent."

Insys Representative: Hi, my name is [XXXX], and I'm with the doctor's office. I never heard an option for me to choose to ... I need to see if a certain medication requires authorization.

Representative from Convey Health Solutions: Ok, can I ... for security purposes can I have your NPI number?

I: It's [XXXX].

R: You say [XXXXX]?

I: Yes.

R: Okay and which doctor is that?

I: It's Dr. Matalon.

R: Okay and for security purposes can you verify the member ID number?

I: Yes, it's ... well, you know what, I have ... I only have their Medicare ID number.

R: Okay, you can go ahead with that number.

I: It's [XXXX].

[...]

* * *

R: Hi [XXXX], thank you so much for holding. Yeah, I'm going to have to connect you to our clinical department so that they can go ahead and try to do that override for you.

[...]

* * *

Envision Clinical Department Representative: Clinical Department, this is [XXXX]. How can I help you?

I: Hi [XXXX], you guys must be very busy people.

E: We are, and I apologize for the long wait, but how can I help you now?

I: I need to know if a certain medication requires authorization, and if it does, can I do it over the phone. It's urgent.

E: Oh okay. You're calling from the doctor's office then, correct?

I: Yeah, Dr. Matalon's office.

[...]

As the conversation with the Envision clinical department representative proceeds, the Insys employee correctly notes that Subsys is "intended for the management of breakthrough cancer pain," but then states only that Dr. Matalon is treating Ms. Fuller for "breakthrough pain." When questioned as to whether Ms. Fuller does, in fact, suffer from breakthrough cancer pain, the Insys employee avoids responding directly and instead explains "there's no code for breakthrough cancer pain." She then states again that the Subsys prescription is "for breakthrough pain, yeah," and the Envision representative discontinues this line of questioning. Toward the end of the call, the Insys employee states that Ms. Fuller is anticipated to remain on Subsys indefinitely.

E: Okay and what is the diagnosis for the patient?

I: Let me look through here [inaudible] ... medication is intended for the management of breakthrough cancer pain. The doctor is treating the patient for breakthrough pain, with a diagnosis code of 338.29—

[...]

E: Thank you. Is it also for the breakthrough cancer pain or not?

I: Well, there's no code for breakthrough cancer pain.

E: Yeah, and that's fine. I typed out the description; I just want to make sure that I heard you correctly.

I: It's for breakthrough pain, yeah.

E: Good. Okay.

[...]

E: And what is the anticipated duration of therapy?

I: Well, there's no end date. I mean, we just try to give her a year and go from there.

E: Okay. And is this a brand or a generic? This is single-source, no generic, so the brand is required.... What other medications in the same therapeutic class have been tried?

I: Okay, they've tried morphine, morphine sulfate.... Let me know if you need me to spell something or go slow, okay?

E: You're doing fine at the pace you're at right now. Morphine sulfate, okay.

I: Oxycodone, OxyContin, and I think that's all I can tell from the notes.

E: Okay, were those ineffective?

I: Yeah, let me see what the note says. It says it had an inadequate analgesic effect. Patient is opioid tolerant.

E: Thank you. And are there any alternatives that are contraindicated, that are not appropriate for the patient? You know, aside from not being effective.

I: That's all that I have.

E: Okay. And this is a spray. Okay.

I: Yeah, it's 200 micrograms. 120 units. For 30 days.

E: And it doesn't look like it's going to have a problem with the quantity limitation. So is there any other clinical information you'd like to provide at this time?

I: No, just that patient will remain on a long-acting opioid and patient is opioid tolerant. Other than that, I think we've covered everything.

[...]

RESPONSE FROM INSYS

The minority staff requested that Insys officials address whether the company implemented the recommendations in the CIS report or took any other action to address deficiencies in prior authorization policies. In response, Insys President and CEO Saeed Motahari provided a letter explaining that the company had "completely transformed its employee base over the last several years," including in "key management positions," and has "actively taken the appropriate steps to place ethical standards of conduct and patient interests at the heart of [its] business decisions."[59] Specifically, Mr. Motahari noted that Insys had "invested significant resources in establishing an effective compliance program with protocols designed to ensure compliant and ethical behavior"; the company also engaged an independent "gap assessment into [its] compliance protocols."[60] In closing, Mr. Motahari pledged "to play a positive and productive role in helping our nation overcome the opioid epidemic."[61]

As part of its ongoing investigation, the minority staff will continue to evaluate whether these efforts have resulted in a true transformation of the Insys corporate culture.

[59] Letter from Saeed Motahari, Insys President and CEO, to Sen. Claire McCaskill (Sept. 1, 2017) (attached as Exhibit C).
[60] *Id.*
[61] *Id.*

CONCLUSION

According to public reporting, lawsuits from Subsys patients, and criminal indictments, Insys Therapeutics has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys. An audio recording and other materials the minority staff has reviewed suggest these efforts have included actions to undermine critical safeguards in the prior authorization process—with Insys officials aware, at the very least, of the serious danger of these acts occurring. The high stakes of opioid overprescription—including patient death—demand close attention to these practices by law enforcement officials, policymakers, and the PBMs charged with approving or rejecting fentanyl treatment.

The PBM Express Scripts excluded Subsys from its list of covered drugs in 2015, and UnitedHealth Group, which owns the PBM OptumRx, did the same in 2016.[62] In December 2016, federal prosecutors indicted Mr. Babich and five other former Insys executives on racketeering charges, alleging that these individuals "approved and fostered" fraudulent prior authorization practices.[63] In June 2017, Ms. Gurrieri, the former head of the IRC, pled guilty "to having conspired to defraud insurers."[64]

On July 17, 2017, shortly after the filing of a complaint by Anthem insurance plans, Insys released a statement explaining that the company has "taken, and will continue to take, appropriate steps to learn from the past and to ensure that appropriate protocols and policies are in place at our Company."[65] As part of its ongoing investigation, the minority staff will continue to evaluate whether these efforts have resulted in a true transformation of the Insys corporate culture.

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[62] *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 4, 2015).
[63] Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).
[64] *Ex-Insys Employee Pleads Guilty in U.S. Opioid Drug Probe*, Reuters (June 19, 2017) (www.reuters.com/article/us-insys-court-idUSKBN19A2MB).
[65] Insys Therapeutics, Inc.: Insys Therapeutics, Inc. Releases Statement on Payor Interactions (July 17, 2017) (www.globenewswire.com/news-release/2017/07/17/1047299/ 0/en/Insys-Therapeutics-Inc-Releases-Statement-on-Payor-Interactions.html).

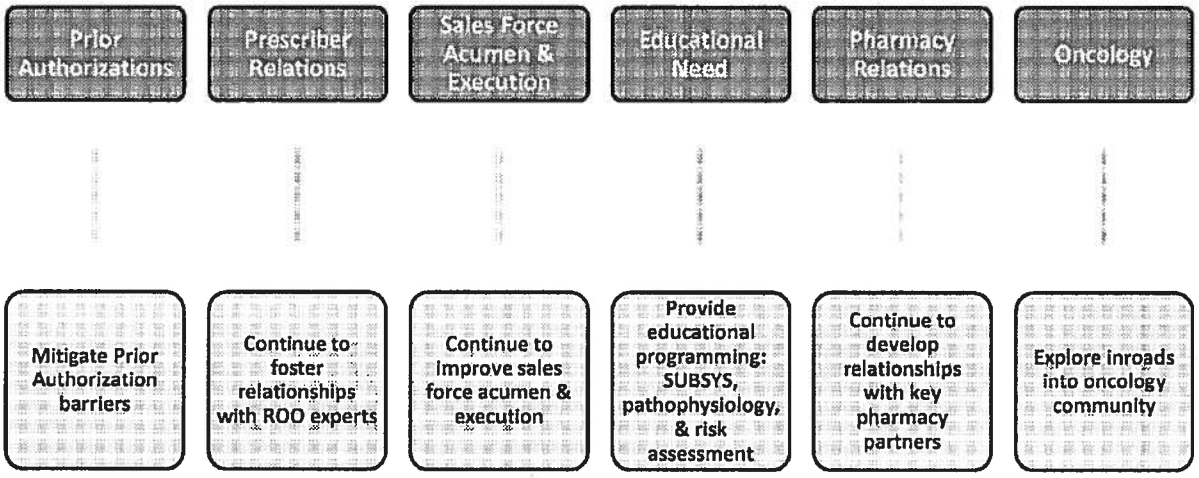
EXHIBIT A

2013 SUBSYS Brand Plan

2012 Assessment

For Planning Purposes Only: Not for Promotion

Key Strategic Imperatives



KSI 1: Prior Authorizations

- Mitigate prior authorization barrier
  - Build internal PA assistance infrastructure
  - Track all PAs via a comprehensive database
  - Establish an internal 1-800 reimbursement assistance hotline
  - Educate field force on PA process and facilitation
  - Partner with PA specialists in key provider offices via best practice ad boards and educational programming
  - Partner with private pharmacies to orchestrate PA logistics
  - Continue to provide Super Voucher during PA navigation

EXHIBIT B

Insys Call Note, Email, & IRC Verbatim Data Audit Report

Presented to

February 18th, 2014

By

Compliance Implementation Services
Ellis Preserve
3809 West Chester Pike, Suite 100
Newtown Square, PA 19073

ATTORNEY CLIENT PRIVELEDGED &CONFIDENTIAL

Table of Contents

Introduction

In mid 2013, CIS was approached by INSYS' legal representative (at that time Leslie Zacks) on behalf of the Board of Directors for INSYS to request that CIS support in the review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how they were being documented. It was communicated at that time to CIS that there was concern with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements of these types of communications. It was also communicated to CIS that while there were no documented examples of this type of interaction to date, the concern stemmed from the lack of monitoring of commercial activities where these types of interactions could occur This was to more specifically include a review of email communications that had occurred (if any) with HCPs by INSYS employees and the documentation process and quality of the call notes recorded after in office meetings with HCPs by INSYS employees had occurred. All of this was to be reviewed against existing INSYS policy and procedure that governed the above discussed activities (if any), interviews with senior leadership to understand more fully any directive given with respect to communications with HPC's, and verifying compliance to them.

It was further requested that a review of the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers occur to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product. All requests ultimately came together to provide a thorough review of internal INSYS email communications with the top twenty (20) SUBSYS prescribing physicians, the call notes that were recorded post an INSYS employee visit with these specific twenty (20) HCPs, as well as an onsite review of IRB operations that included interviews, live monitoring, and a review of existing policies and procedures (if any) governing the actions of those working within the IRC.

CIS is pleased to present the following observations and recommendations found within this report.

Project Objective and Scope

Objective:
The objective of this audit was to evaluate and assess the existence, adequacy, and comprehensiveness of INSYS's existing policy and procedural documentation to determine whether adequate controls were in place to effectively ensure compliance and adherence to said documents, INSYS guidance, and industry best practices related to all forms of communication from INSYS employees to HCPs.

Specifically, the objective of this audit was to review sales representative call notes and other communications and documentation to ensure oversight of day-to-day promotional and non-promotional activities and to ensure prospective compliance with the INSYS policies, procedures, and communicated controls (if any). Further, the objective of this review was to ensure that the IRC's communications were in alignment with INSYS and IRC specific policies, procedures, and communicated controls (if any) regarding interactions with HCP's, as well as on label with respect to product indication.

HCP & IRC Scope:
The project sponsors both Leslie Zacks and Desiree Hollandsworth at the request of the INSYS Board of Directors and in conjunction with the CIS team, narrowed the scope of the engagement to specifically target all communications, interactions, and documentation with the top twenty (20) prescribing HCPs for INSYS'

commercially marketed product, SUBSYS. Further, the scope of data and document review of the IRC interactions with HCPs was to be narrowed to a random sampling of live phone calls, interviews with employees and management, and review of existing policy, procedure, and SOPs (if any) governing the actions of the IRC and its employees.

Documentation, Interview, & Live Monitoring Scope:
CIS reviewed the following policies and procedures that INSYS provided related to their internal requirements governing interactions with HCPs, the documentation of HCP visits within the INSYS Sales Force 360 platform (call note repository), and the IRC. CIS also collected functional data for the audit which is listed below. Finally, CIS scheduled interviews with the below listed INSYS employees to obtain a better understanding of processes and requirements as they related to HCP communication and documentation both in the field and the IRC. It should be noted that during the onsite IRC visit there were employees on vacation and or out of the office, so multiple calls were monitored for the same employee. CIS would like to note that the recording and transcripts of the live monitoring session was not possible to obtain, as currently INSYS does not have the ability to do so with its current phone system.

Document Type	Title
Governance	INSYS Code of Business Conduct
Governance	Compliance Program and Certification of Compliance
Governance	INSYS Employee Handbook
SOP #4	Insurance Reimbursement Center Communication Process
SOP #3	INSYS Reimbursement Center Line
SOP #2	INSYS Reimbursement Center
SOP #1	30 Units Free and Super Vouchers
PPT – Training	Overview of IRC Impact
Document	IRC At-A-Glance
PPT – Training	Prescription Process Flow Chart
PPT – Training	PA Workshop (New Hire Training and Refresher Training)
PPT – Training	IRC Sales Force Training
Internal Document	New Opt-In Form
Internal Document	IRC Flow Chart – Appeal Process
Internal Document	IRC Flow Chart – PA Process
Corporate Email	Multiple Internal IRC Emails with directives from management on numerous topics
PPT – Training	Revised Core Speaker Deck
PPT – Training	Supplemental Speaker Deck Slides
PPT – Training	New Sales Force Training curriculum
HCP Data	Top twenty (20) HCP Prescriber data excel files (2)
Call Notes Data	All call notes associated with the top twenty (20) HCP Prescribers for 2013
Corporate Email Data	Email communications associated with the top twenty (20) HCP Prescribers -2013

INSYS Employee Interview	Date
Desiree Hollandsworth – Marketing/Communication	October 27th, 2013, November 15th, 2013, December 19th 2013
Leslie Zacks – Legal	October 27th, 2013
Maury Rice – IT	December 19th, 2013
Mike Gurry – Managed Markets (IRC)	December 18th, 2013
Liz Gurrieri – Managed Markets (IRC)	December 18th, 2013

Darin Fila - Sales Training	December 19th, 2013

INSYS IRC Employee – Live Monitor	Date
Allyson Fulton	December 18th, 2013
Sam Renzetti	December 18th, 2013
Traci Giles	December 18th, 2013
Allyson Fulton	December 18th, 2013
Patricia Ray Nixon	December 19th, 2013
Patricia Ray Nixon	December 19th, 2013
Sam Renzetti	December 19th, 2013
Traci Giles	December 19th, 2013
Allison Fulton	December 19th, 2013
Traci Giles	December 19th, 2013

Project Methodology

The audit focused on evaluating any existing written documentation that governs appropriate communication with HCPs as an INSYS employee and whether or not there are adequate controls in place that effectively ensure compliance and adherence with said documentation, INSYS guidance, and industry best practices related to HCP communication and interactions.

The methodology outlined below was used for the Call Notes, Email, and IRC Verbatim Audit Report:

FIELD WORK & GENERAL OBSERVATIONS

- ***Document Collection, Review, and Interviews***
  CIS collected and reviewed various documents provided by INSYS as well as carried out interviews with key stakeholders to better understand specific processes in place with respect to HCP interactions and communication. These documents and interviews are listed in the Documentation and Interview scope section above and include, but are not limited to:

  I. *Policies and Procedures*
  INSYS has various policies and procedures in p lace that provide certain instruction for compliance and governance related to appropriate interactions and communications with HPCs. The documentation listed above was reviewed and covered both organization wide requirements as well a s business unit specific; specifically those governing the IRC and its employees.

  II. *Call Notes Repository (Salesforce 360), Corporate email account platform*
  INSYS provided CIS with one (1) year worth of call notes associated with the top twenty (20) SUBSYS prescribing HCPs to assess whether the calls were recorded in a manner consistent with INSYS communicated guidance, policies and procedures. INSYS also provided CIS with one (1) year worth of corporate email data associated in some way to the top twenty (20) HCP prescribers of SUBSYS listed by INSYS, to review and ensure appropriate communication with HCPs via email per INSYS communicated guidance, policy, and procedures.

  III. *IRC Specific Work Instructions and Governance Documentation*
  INSYS provided CIS with all existing documentation that governs the work process es, templates, SOPs, and expectations on how to appropriately engage HPCs or their staff, Health

Care Insurers, and other third party entities that may be part of a conv ersation regarding IRC support and proper doc umentation of those engagements with the ultimate goal of supporting patients in obtaining a Prior Authorization (PA) for an INSYS marketed product.

IV. *IRC Interviews, Live Monitoring, and Walkthroughs of current requirements*

CIS met with Mike Gurry, Vice President Managed Markets , and Liz Gurrieri Manager Managed Markets, on December 1 8th, 2013 to review the IRC support process and gain a more in depth understanding of the specific roles and responsibilities of the IRC staff, as well as the general procedures which occur daily with respect to HCP and Health Care Insurer (HCI) interactions and how specific support to gain a PA is obtained. CIS also was present for the live monitoring of ten (10) calls made by IRC representatives, both incoming and outgoing in support of obtaining a PA for patients. After each call, CIS asked the IRC representative to walk them through the process flow of the particular type of call, and the expected documentation to be on file with it. Further, the CIS monitor spoke with Liz regarding the current auditing and monitoring of IRC associate calls, and what processes were in place to ensure adherence to INSYS and IRC communicated guidance , policy, and procedures regarding HCP interaction and communication. It was apparent to the CIS monitor during the live telephone interactions that the IRC staff was adequately trained with respect to HCP, HCI and I RC employee communication standards. All employees conducted themselves in a professional manner and no deviance from INSYS or IRC controls was observed.

- ***Indentified Existing Key Document Controls***

CIS indentif ied that some key controls related to the appropriate communicati on and interaction with HCPs were in place through the documentation review process. Additionally, CIS determined that some of the submitted IRC communications , procedures, and governance documentation su pported in the training and adherence of IRC personnel to INSYS and IRC communicated guidance and industry be st practices related to the specific HCP and HCI interactions that occur . CIS also noted upon review of the call notes provided for the audit, that all HCP interactions were filled out completely using the required drop down descriptions, and incomplete or partial entries were not found.

- ***Identified the Lack of Formal and Approved Governance Documentation, Policy, Procedures, and SOPs***

CIS identifie d that while documentation with respect to communication and inter actions with HCPs existed, there were also gaps in formally approved foundational policies, procedures, and SOPs with respect to required processes specifically within the IRC. CIS also ide ntified the lack of a formal policy with respect to email communic ation from a sales representative to an HCP and the appropriate and approved methods by which they are to occur.

- ***Identified the Absence of an Auditi ng & Monitoring Function Within Multiple Business Units as Well as Through Interviews with Key INSYS Stake Holders***

During the interviews held with INSYS employees, it was apparent that no quality assurance processes were in place to monitor or audit the actions of sales representatives with respect to a timely call note record creation of an HCP visit within the Sales Force 360 platform. Further, there were no plans communicated to CIS with respect to implementing an auditing and monitoring function to ensure adherence t o communications wit h this action. Further, through interviews it was apparent that no specific email monitoring process was in place and documented with respect to corporate email communication and HCPs in general, and specifically those that may occur f rom a field sales

representative to an HCP. Finally, through interviews with the IRC management, there was no formal, documented, or detailed process by which IRC representatives ' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion other than random physical review of a call in a very informal and sporadic manner.

Specific Observations and Recommendations

Based on the audit procedures performed that related to the Verbatim Data Audit Process, CIS is providing the following specific observations and recommendations identified as a result of the review and audit performed.

All observations and recommendations are based on compliance coverage for adherence to INSYS communicated guidance, policies, and SOPs, as well as benchmarking against industry best practices.

Observation #1: Upon reviewing the training curriculum with respect to sales representatives entering in call notes post an HCP visit, as well as any associated written requirements, interviews with INSYS Marketing Communication and Sales Training employees, the following observations were made:

- *Observation 1-1:* While sales representatives are required to record a call note for each visit made to an HCP, governance documentation and training generally lack specificity on the time frame a representative has to input the call note by.
- *Recommendation 1-1*: The requirement to input a call note for an HCP visit within an INSYS approved time frame should be pronounced during trainings, and specifically called out within procedural guidance for inputting HCP call notes. It is recommended that a "Documentation of HCP Communication" SOP be created, approved, and disseminated.

- *Observation 1-2*: No formal auditing and monitoring process currently exists to ensure that sales representatives are inputting call notes within a specified time frame post and HCP visit.
- *Recommendation 1-2*: CIS recommends that a job description and requirement be added to District Managers and above to periodically review the call note input date within the Salesforce 360 platform to ensure that they are in alignment with INSYS requirements for call note creation post an HCP visit. These audits to be retained for performance review issues, further training when deemed necessary, and in some cases disciplinary action.

Observation #2: Upon initiating the corporate email review and assessing how to query any communication from INSYS employees with the top twenty (20) HPC prescribers of SUBSYS, it became apparent that due to the extremely high volume of email search hits that came back under keyword queries, (all of which consisted of internal emails discussing HCP engagements or mention of the HCP's name) a random sampling of each of the twenty (20) top HCP SUBSYS prescribers would serve as a more realistic sample. The randomly sampled emails were reviewed for adherence to INSYS communication and interactions with HCPs documentation, as well as specific INSYS communicated guidance with respect to email communication and HCPs. Many multiple thousands of emails were produced over a year's time frame, which presented a challenge for the IT department when searching and categorizing them. For the size and scope of this particular review, CIS chose to randomly sample one hundred (100) emails from each of the top twenty (20) HCP SUBSYS prescribers to ensure all communication was in alignment with INSYS policy, procedure, and appropriate in nature.

Out of the two thousand (2000) randomly selected emails (100 for each of the top twenty (20) HCP prescribers of SUBSYS); no direct email was found between a sales or field representative and an HCP. Any direct email communication with the HCP was engaged by a member of the Marketing, Executive, or Senior Management team and found appropriate in nature. CIS would like to note that the majority of reviewed emails consisted of internal INSYS discussions with respect to that particular HCP and all appropriate in nature.

Recommendation: Although no inappropriate communication or violation of INSYS policy around HCP communication was found, CIS does recommend that a corporate compliance auditing and monitoring function be created and implemented to ensure periodic reviews of HCP email communication as on ongoing monitoring activity. This will ensure a much more up to date picture of communications between HCPs and INSYS employees in general, and also serve to satisfy the Office of Inspector General's specified element of an effective compliance program, by have this function ongoing. CIS also recommends that while sections of the INSYS Employee Handbook and Code of Ethics do discuss appropriate interactions with HCPs, a separate and distinct "Interactions with Health Care Professionals" policy should be drafted and disseminated company wide.

- *Observation 2-1:* During the interview process, CIS learned that INSYS field sales representatives are prohibited from emailing HCPs, and communication was to be restricted to in-person, telephone, or text messaging only. There was no policy found to support this requirement.
- *Recommendation 2-1:* A separate and distinct policy should be created that outlines the approved methods of communication with HCPs as they relate to INSYS employees, and specifically the sales representatives to ensure accountability and establish a baseline standard of communication that can be measured.

- *Observation 2-2:* No formal auditing and monitoring process currently exists to ensure that email communications between HCPs and INSYS employees are both appropriate and professional in nature, as well as being initiated and sent solely by an authorized INSYS employee.
- *Recommendation 2-2:* CIS recommends that INSYS incorporate and auditing and monitoring function, as well as system controls within the corporate email server that can notify appropriate levels of management when a key word or HCP name is scanned. This will serve as a monitoring tool for compliance to communication standards as they relate to HCP interactions.

Observation #3: CIS observed that there was a specific lack of formal and approved policies, procedures, and SOPs that govern the actions of the IRC. Upon review of submitted IRC documentation and interviews held with IRC representatives, the following observations were made:

- *Observation 3-1:* No formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, HCIs, or patients exists (or wasn't supplied to CIS for review) that governs the support function of obtaining a prior authorization for the use of SUBSYS.
- *Recommendation 3-1:* INSYS IRC management to formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs.

- *Observation 3-2*: CIS observed that four (4) informal SOPs existed (see document scope section) but lacked a formal review and approval, as well as specificity with respect to the referenced topic. CIS noted that the documents were most likely white papers or narrative flow charts of processes, but no formal and approved SOPs exist (or weren't supplied to CIS for review) that outline appropriately the actions performed within the IRC.

- *Recommendation 3-2*: INSYS IRC management to formally draft and obtain proper review and approval of IRC specific SOPs that in a detailed and action specific manner will govern all processes engaged within the IRC. INSYS IRC management should ensure these SOPs are specific to each job function within the IRC and that once formally reviewed and approved, adequate training and understanding of these processes exists.

- *Observation 3-3:* While a quality control function does exist with respect to IRC documentation regarding the Opt-in program and patient file information, no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients.
- *Recommendation 3-3:* INSYS IRC management to formally draft and obtain proper review and approval of an IRC Auditing & Monitoring specific policy and SOP. Further a specific schedule to monitor both live and anonymously IRC employee communications both incoming and outgoing and at any given time should be created and adhered to. This function will serve to ensure adherence to IRC communication standards and serve as supporting documentation for training, annual reviews, and if necessary disciplinary action. It is recommended that the INSYS IRC implement an electronic system that will allow management to listen to calls in real time to ensure total anonymity.

Observation #4: Upon review of submitted IRC documentation (CIS requested all governance documentation in general that could be reviewed), CIS noted the following:

- *Observation 4-1:* The majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast, and in some reviewed document submissions, updates or changes to existing templates and documents were copy and pasted into the body of emails and disseminated for immediate use.
- *Recommendation 4-1:* INSYS IRC management to formally implement a change control process by which standardized documents, templates, and IRC documentation used for patient and HCP data may be revised or updated in a formal, approved method that is in alignment with existing INSYS change control and documentation creation and revision policies and guidelines. This is industry best practice and will allow for periodic review of file audits to ensure the most up to date templates are in use.

Conclusion

This audit report supports an ongoing acknowledgement by INSYS of the need to conduct continual monitoring activities to ensure Policies, Standard Operating Procedures, and industry best practices exist and are adhered to within the organization and throughout various business units. INSYS recognizes its responsibility in monitoring company activities and as such requested this specific audit as a means to assist in its ongoing monitoring of communication and interactions between HCPs, HCIs, and other affiliated entities and INSYS employees from both the corporate side, as well as the commercial or field force side of the business.

Throughout the review of INSYS wide email communications with specific HCPs and the documentation of interactions with specific HCPs via call note creation and entry by sales representatives, CIS concluded that while there lacks specific policies as well as auditing and monitoring procedures, (see recommendations section) very few adverse observations were noted, and no major violation of INSYS communicated guidance or governance documentation existed. The following points were also noted:

- There is sound compliance to documenting appropriately interactions with an HCP via a call note within the SalesForce 360 platform. There were no instances of non-compliance or incomplete entries found upon review, and the INSYS sales force should be commended for their dedication to this requirement.
- Out of 2000 reviewed emails that all referenced a specific subset of high SUBSYS prescribing HCPs, there were no instances of inappropriate communication or discussion found as they related to off-label promotion of a product or use, and no violation of INSYS policy with respect to email communication with HCPs and specific job titles namely sales representatives.
- Upon monitoring ten (10) IRC associate conversations with HCPs, their office staff, and insurance carriers with respect to the authorization and use of SUBSYS, CIS noted that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated.

Despite changes in original scope of this engagement, and specific review requests such as not being able to record IRC employee conversations while on the phone anonymously due to the lack of technology, and the unexpected volume of emails referencing a specific sub set of high SUBSYS prescribing HCPs, the Call Notes, Email, and IRC Verbatim Data Audit was completed and found to be exemplary in the minimal amount of specific findings and recommendations noted. In conclusion, CIS recommends that all types of communication, interaction, and documentation between HCPs and INSYS employees be associated with a governing policy and SOP, to ensure compliance to clear and concise INSYS communicated guidance and standards. CIS also recommends that an auditing and monitoring function across the reviewed areas be implemented immediately to ensure a constant and ongoing review of interactions and communications between HCPs and INSYS employees, and that they are in compliance with formally drafted and approved governance documentation.

– End of Report

EXHIBIT C

INSYS THERAPEUTICS, INC.

September 1, 2017

The Honorable Claire McCaskill
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Re: Insys Therapeutics, Inc.

Dear Senator McCaskill:

As you and your staff continue to review certain aspects of the commercial practices of Insys Therapeutics, Inc. ("Insys"), I would like to assure you that I stand with you and share the desire to address the serious national challenge related to the misuse and abuse of opioids that has led to addiction and unnecessary deaths and has caused so much pain to families and communities around the country.

Four months ago, I joined Insys after undergoing my own due diligence process and coming to the understanding that this company has great potential to assist patients in unmet medical needs. Like you and your staff, I was concerned about certain mistakes and unacceptable actions of former Insys employees that have been disclosed and discussed in public forums over the past several years. These mistakes and actions are not indicative of the people that are currently employed at Insys and I share your belief that the "vast majority of the employees, executives, sales representatives, scientists, and doctors involved with this industry are good people and responsible actors" including our employees. In this regard, Insys has completely transformed its employee base over the last several years. Notably, over 90% of the 250 field-based sales staff employed prior to 2014 are no longer with the organization. Even in the limited time since I joined the company, we have hired over 50 new employees and replaced key management positions including the following leaders:

- President and Chief Executive Officer
- Chief Financial Officer
- Vice President of Sales
- Regional Director of Sales
- Vice President of Marketing and Managed Care
- Senior Director of Commercial Operations
- Vice President of Medical Affairs
- Senior Director, Clinical Development Medical Affairs (a pain and addiction specialist)

Over the past several years, Insys has actively taken the appropriate steps to place ethical standards of conduct and patient interests at the heart of our business decisions. Our compliance program has been under significant scrutiny for several years from both governmental authorities but also as a result of internal reviews conducted with the assistance of external experts and counsel. During this period, we have invested significant resources in establishing an effective compliance program with protocols designed to ensure compliant and ethical behavior. We recently completed a successful gap assessment into our compliance protocols and processes by an independent, global consulting firm. This assessment was voluntarily conducted with oversight from our Compliance Committee of the Board of Directors. We

INSYS THERAPEUTICS, INC.

passionately believe that the company has taken necessary steps to ensure that we will not repeat the mistakes of the past.

Notwithstanding these transformative changes, as the Chief Executive Officer of Insys and a member of its board of directors, I believe that it is imperative that we take responsibility for the actions of our former employees. This belief is strongly shared by our board of directors. Insys continues to strive to do that where the facts and circumstances dictate that we do so.

I write to you today on behalf of over 400 employees, across three facilities including a research and development laboratory and a fully functional manufacturing facility who have worked tirelessly to develop and manufacture our two FDA-approved products approved for the conditions of breakthrough pain in cancer patients, nausea and vomiting associated with chemotherapy and weight loss in AIDS patients. These products fulfill a significant unmet need for patients requiring supportive or palliative care as they fight their battle with cancer or AIDS. These employees, many of whom have advanced and doctorate level degrees in the technical and health sciences are working diligently every day to develop new medicines and therapies to treat severe catastrophic diseases such as intractable pediatric epilepsy, rare genetic diseases such as Prader-Willi Syndrome, life-threatening anaphylaxis reactions, opioid overdose, opioid addiction & dependence, agitation in Alzheimer's Disease and anorexia in cancer patients. It is worth noting that since 2012, Insys has invested over $170 million in research and development to advance our pipeline and make a positive impact in the lives of patients and caregivers.

Like so many stakeholders in healthcare and government, we hear the call to action to address the nation's opioid crisis. The opioid epidemic is a highly complex and multi-faceted issue requiring a solutions based approach. We stand ready to help address this public health crisis collaboratively through educational initiatives and drug monitoring programs centered around patients, caregivers, healthcare providers and the overall community. We feel strongly that to develop a solution we must first understand and correct the drivers of the problem.

SUBSYS® is one of six pharmaceutical products in a class called Transmucosal Immediate Release Fentanyl (TIRF). A doctor is not permitted to prescribe, a pharmacy is not permitted to dispense, and a patient is not permitted to receive any TIRF product, including SUBSYS®, unless each of them is enrolled in the Food and Drug Administration ("FDA") mandatory TIRF Risk Evaluation and Mitigation Strategy ("REMS") program. The TIRF-REMS program strives to limit the risk of abuse and misuse by restricting prescriptions to appropriate patients, preventing inappropriate conversions between medicines and educating patients, pharmacists and prescribers about potential for abuse, addiction and overdose of TIRFs, as well as the label for these products.

In 2016, there were 215 million opioid prescriptions written in the United States. SUBSYS® accounted for approximately 34,000 (less than 0.02%) of these prescriptions nationally. These 2016 prescription numbers for SUBSYS® place Insys below the top 50 manufacturers of opioids in the United States. When considering fentanyl's role in the current opioid crisis, it is important to note that in the National Heroin Threat Assessment Summary issued in June 2016, the Drug Enforcement Administration concluded that "pharmaceutical fentanyl is diverted for abuse in the United States at small levels" and recent overdose deaths from fentanyl are "largely due to clandestinely-produced fentanyl, not diverted pharmaceutical fentanyl."

insys THERAPEUTICS, INC.

From a personal perspective, we all have been touched or been affected by cancer—as a patient, caregiver, friend, family member or loved one. An aspect of cancer that can be easily overlooked and greatly underappreciated is the excruciating pain that often accompanies the disease as it progresses and is associated with surgical, radiation and chemotherapy treatment. For some patients, the breakthrough cancer pain or cancer related pain can be debilitating and devastating. We would be willing to share with you some of the experiences of patients who have benefited from SUBSYS®. Their experiences illustrate the importance of addressing and treating breakthrough cancer pain appropriately.

I sincerely welcome an opportunity to engage in a meaningful dialogue and partner with key stakeholders such as yourself, other Senators and professional consortiums to play a positive and productive role in helping our nation overcome the opioid epidemic.

Respectfully,

Saeed Motahari
President & Chief Executive Officer
Insys Therapeutics, Inc.

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